UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: Bair Hugger Forced-Air Warming Devices Products Liability Litigation	File No. 15-MD-2666 (JNE/FLN)
	Thursday, May 18, 2017
	Minneapolis, Minnesota
	Courtroom 9 West
	9:30 A.M.

(HEARING ON MOTIONS)

BEFORE THE HONORABLE FRANKLIN L. NOEL
UNITED STATES MAGISTRATE JUDGE

- and -

THE HONORABLE WILLIAM H. LEARY, III
RAMSEY COUNTY DISTRICT COURT JUDGE

TIMOTHY J. WILLETTE, RDR, CRR, CRC
Official Court Reporter - United States District Court
1005 U.S. Courthouse - 300 South Fourth Street
Minneapolis, Minnesota 55415
612.664.5108

A P P E A R A N C E S:

For the Plaintiffs:

MESHBESHER & SPENCE, LTD.
By: GENEVIEVE M. ZIMMERMAN, ESQUIRE
1616 Park Avenue South
Minneapolis, Minnesota 55404

CIRESI CONLIN, LLP
By: JAN M. CONLIN, ESQUIRE
MICHAEL A. SACCHET, ESQUIRE
225 South Sixth Street - Suite 4600
Minneapolis, Minnesota 55402

KIRTLAND and PACKARD, LLP
By: BEHRAM V. PAREKH, ESQUIRE
2041 Rosecreans Avenue - Third Floor
Suite 300
El Segundo, California 90245

KENNEDY HODGES, LLP
By: GABRIEL A. ASSAAD, ESQUIRE
4409 Montrose Boulevard
Houston, Texas 77006

FARRAR & BALL, LLP
By: KYLE W. FARRAR, ESQUIRE
1010 Lamar - Suite 1600
Houston, Texas 77002

For the Defendant 3M:

BLACKWELL BURKE, P.A.
By: JERRY W. BLACKWELL, ESQUIRE
MONICA L. DAVIES, ESQUIRE
BENJAMIN W. HULSE, ESQUIRE
COREY L. GORDON, ESQUIRE
431 South Seventh Street - Suite 2500
Minneapolis, Minnesota 55402

FAEGRE BAKER DANIELS, LLP
By: BRIDGET M. AHMANN, ESQUIRE
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, Minnesota 55402

A P P E A R A N C E S: (Continued)

For Dr. Scott Augustine:

J. RANDALL BENHAM, ESQUIRE
6581 City West Parkway
Eden Prairie, Minnesota 55127

For movant Ridgeview Medical Center:

MELCHERT HUBERT SJODIN, PLLP
By: KELLY C. DOHM, ESQUIRE
121 West Main Street - Suite 200
Waconia, Minnesota 55387

(*Various participants via telephone*)

*** * * ***

(9:30 a.m.)

P R O C E E D I N G S

IN OPEN COURT

MAGISTRATE JUDGE NOEL: Good morning. Please be seated.

JUDGE LEARY: Good morning, everyone.

MAGISTRATE JUDGE NOEL: Okay. So this is In Re: Bair Hugger Forced-Air Warming Devices Products Litigation. Judge Leary and I are both presiding over this hearing which will be a joint proceeding between the MDL and the Ramsey County cases that are proceeding.

We're here for a hearing on three things. The first is the plaintiffs' motion to add a claim for punitive damages, which is ECF number 307 in the MDL; the defendants' motion to de-designate documents under the protective order, which is ECF number 393 in the MDL; and the defendants' motion for additional deposition time, which is docket entry number 411 in the MDL.

So let's start with the plaintiffs' motion to add the claim for punitive damages. I'm sorry. Let's start by getting everybody's appearance on the record.

MR. HULSE: Your Honor -- Ben Hulse, by the way, for Defendants.

As a housekeeping thing, we reached out yesterday raising a request to exclude third parties from the

courtroom for this motion given that there's going to be discussion of under-seal materials, and so we're making that request formally on the record today.

MAGISTRATE JUDGE NOEL: Okay. Bear with me one second.

(Discussion off the record between Magistrate Judge Noel and Judge Leary)

IN OPEN COURT

MAGISTRATE JUDGE NOEL: First, let me observe we have all these folks on the telephone. The courtroom is the property of the people of the United States.

What authority do you rely on -- actually, before we even get to that, let's get everybody's appearance on the record so that we're -- and then I'll come back to Mr. Hulse.

MS. CONLIN: Good morning, Your Honors. Jan Conlin from Ciresi Conlin on behalf of the plaintiffs.

MS. ZIMMERMAN: Good morning, Your Honors. Genevieve Zimmerman from Meshbesher & Spence, also on behalf of Plaintiffs.

MR. SACCHET: Michael Sacchet on behalf of Plaintiffs.

MS. DOHM: Kelly Dohm on behalf of Ridgeview Medical Center.

MR. BENHAM: Representing Dr. Scott Augustine,

J. Randall Benham.

MAGISTRATE JUDGE NOEL: Anybody else from the plaintiffs want to --

MR. PAREKH: Behram Parekh on behalf of Plaintiffs.

MR. ASSAAD: Gabriel Assaad on behalf of the plaintiffs.

MR. FARRAR: Kyle Farrar on behalf of Plaintiffs.

JUDGE LEARY: I'm sorry. Counsel for Ridgeview, could you spell your last name, please.

MS. DOHM: Yes, Your Honor. It's D-O-H-M. My first name is Kelly, K-E-L-L-Y. I'm with the firm of Melchert Hubert Sjodin.

JUDGE LEARY: Thank you.

MR. BLACKWELL: Good morning, Your Honors. Jerry Blackwell, Blackwell Burke, speaking on behalf of 3M and Arizant.

MS. DAVIES: Good morning, Your Honors. Monica Davies, also with Blackwell Burke. I'm here on behalf Defendants.

MR. GORDON: Good morning, Your Honors. Corey Gordon, Blackwell Burke, also for 3M and Arizant.

MR. HULSE: Good morning, Your Honors. Ben Hulse on behalf of Defendants.

MS. AHMANN: Bridget Ahmann, Faegre Baker Daniels,

on behalf of 3M and Arizant.

MAGISTRATE JUDGE NOEL: All right. And Mr. Hulse, why don't you come to the podium.

MR. HULSE: Yes. (Approaches podium).

MAGISTRATE JUDGE NOEL: Both Judge Leary and I had a question as to what authority you're relying on for excluding folks from the courtroom.

MR. HULSE: Yes, Your Honor. An Eighth Circuit case, ***In re Iowa Freedom of Information Council***, 724 F.2d 658, 664, recognizing that district courts can close proceedings to protect a party's trade secrets or sensitive business information; also ***In re St. Jude Medical***, 2001 Westlaw 1663818 from 2001, similar authority.

There is information in some of the exhibits that Plaintiffs have presented in support of this motion that qualified for protection under the protective order entered into in this case, in particular that it is competitively sensitive: planning information, internal research and development information in particular. And this is a particularly significant concern because of the other motion that we have here with Mr. Benham, who is counsel for Augustine, Augustine being, of course, a competitor of 3M and formerly Arizant in the patient warming market.

So that's our legal authority, the factual basis for our request, too, and that's why we're asking for

counsel for Augustine and also counsel for Ridgeview to be excluded, but in particular our concern has to do with counsel for Augustine.

MAGISTRATE JUDGE NOEL: Ms. Conlin?

MS. CONLIN: Sure. The case that Mr. Hulse just cited is an Eighth Circuit case that deals with trade secrets. I don't know -- and you've seen the exhibits. There's nothing in the exhibits themselves that is suggestive of a trade secret.

I understand why they would like to have the courtroom -- exclude anyone other than the parties, because some of the information is quite damaging to 3M, but that doesn't -- that's a separate issue than whether it gives rise to trade secrets or not.

JUDGE LEARY: Here's what my concern is given the fact that this is a joint hearing with Ramsey County.

Court hearings are public events, and the last time I looked at the rules that applied to court proceedings in the state of Minnesota, it requires that notice be given of an intent to request a closed hearing and that's not been given in this case. And regardless of whether or not that rule with which I've been previously familiar applies in this case, why wasn't prior notice of this request given?

MR. HULSE: Well, Your Honor, pursuant to -- I agree that the Ramsey County rule that you're citing, to the

extent it required notice to yourself, Your Honor, we did not give it.

JUDGE LEARY: It requires public notice as well.

MR. HULSE: And the protective order in this case has a requirement to give -- to raise the issue with the court in advance, and we did contact Judge Noel's chambers in advance and were advised to raise it here at the hearing, for what that's worth. But obviously, we appreciate fully the public's right to access to the courtroom and this has nothing to do with information being damaging. We strongly dispute that. It's simply that in particular, as the Court is aware from the briefs and the information submitted, there is internal R&D information that would rise to the level of trade secret that is presented in the plaintiffs' papers, and that really shouldn't be disclosed to counsel for Augustine, a competitor, simply because we happen to have another motion up today.

JUDGE LEARY: And I have a follow-up question.

The information that you're concerned about, is that information that's already part of the court record?

MR. HULSE: Under seal, Your Honor, yes.

JUDGE LEARY: So these documents have been filed under seal in Ramsey County?

MR. HULSE: Correct, Your Honor.

MAGISTRATE JUDGE NOEL: One last question on the sealing thing, and I think I know the answer, but I'm going to ask it anyway.

Under our new local rule about filing under seal, is there already on file the follow-up joint motion to continue the sealing or not?

MR. HULSE: No, Your Honor, because it's not due yet for another two weeks from today. Because last Thursday was the final filing in support of the motion and so it's due in three weeks. We recognize that there may be -- that some of these materials will get unsealed through that process.

MAGISTRATE JUDGE NOEL: Okay. So Judge Leary and I have briefly talked about the request to exclude people from the courtroom and to close the hearing, even if partially, and that request is denied.

So let's move then to the plaintiffs' motion to amend the claim for punitive damages.

Ms. Conlin, you're up.

MS. CONLIN: Sure. I've got a PowerPoint. May I pass up copies, Your Honor?

(Documents distributed to the Courts and counsel)

MS. CONLIN: Good morning, Your Honor.

While my colleague gets the PowerPoint up on the monitor, I'd like to start first with this issue of choice

of law. And frankly, we thought in light of Chief Judge Tunheim's decision in ***Levaquin***, finding that the Minnesota punitive damages statute is remedial and thus no conflict-of-law analysis needs to be performed, Defendants have raised it. And I think the holding of that case makes very clear that in Minnesota, the procedural rule requiring filing of a motion before amending for punitive damages is a procedural rule.

And in fact, in the ***Levaquin*** case, unlike this case, the defendant was a New Jersey defendant, and the court there found that in fact Minnesota's interest in protecting people within its state by corporations who do business in this state was sufficient for the Minnesota punitive damages statute to apply.

The other issue I just raise is with respect to the bellwether plaintiffs. All of those plaintiffs have consented to Minnesota jurisdiction, so this will be the forum state for the purposes of those bellwether trials.

If the Court has other questions on that?

MAGISTRATE JUDGE NOEL: Yeah. How many states are represented in the MDL?

MS. CONLIN: I think virtually 36 or 38 states.

MAGISTRATE JUDGE NOEL: And how many of those states have a requirement that there be some level of showing before permitting the pleading of a claim for

punitive damages?

MS. CONLIN: Have not done that analysis, Your Honor, but we did look at the eight bellwether cases. Three states implicated: Minnesota, Wisconsin, and Florida. Those all have the same statute as Minnesota, and in fact, Your Honor found that in the ***Mirapex*** case.

South Carolina, Kentucky, and Idaho are the other three. South Carolina and Kentucky don't require any motion to plead punitive damages. In other words, you can do it out of the gate. And Idaho does require it, but it's actually a less strict standard than in Minnesota.

MAGISTRATE JUDGE NOEL: Okay.

JUDGE LEARY: In terms of the state court action, I assume that there is no conflict-of-law issue, is that correct?

MS. CONLIN: There is none, Your Honor.

JUDGE LEARY: Okay.

MS. CONLIN: So I'd like to talk a little bit about the standard for making a motion to amend for punitive damages.

And in fact, if you look at the brief that was filed by 3M, it basically is: We don't think the evidence says what you say it is, and those are classic examples, both in ***Mirapex***, ***Levaquin***, and ***Prempro***, where the court has said on the motion to amend for punitive damages, you can't

look at the rebuttal evidence or what spin a defendant wants to put on it. We think that's true here. In ***Levaquin*** the court makes no credibility rulings and does not consider any challenge by cross-examination or otherwise to the plaintiffs' proof, and that's in fact the case here.

So I would like to bring the Court back a little bit to science day. At science day we talked with this Court about the chain of infection.

It's Plaintiffs' belief -- and we think the evidence bears this out -- that the Bair Hugger is defectively designed. It sucks up microbes and bacteria. In Dr. David's report it had the -- showed that if you put paper by the machine and turn it on, it sucks the paper up next to the vents on the machine.

So the chain of evidence for infection is that the Bair Hugger doesn't adequately filter air, sucks it up off the floor of the OR, spews it into the surgical site, and in fact also creates because of the heat generated by the machine, creates convective current which brings turbulent air and dirty air from below the surgical table into the surgical site.

And in this case we're alleging that particularly in orthopedic surgeries where an implant is going to be put into a patient -- and Dr. Jarvis talks about it in his report; we presented it at science day -- it only takes one

or two microbes to land on that implant during surgery to cause a surgical site infection or a deep prosthetic joint infection. No one knows it's there, the wound is closed up, and some months later when the biofilm develops, the patient develops a deep infection, and that's the case here.

So in this case what do we have by way of *prima facie* evidence? We submit to Your Honors that the evidence that we submitted in connection with our briefs is exactly within the types of buckets of evidence that courts in Minnesota have said is sufficient to allow us to amend for punitive damages.

Failure to warn about the risks. I'm going to show you some documents out of our brief where they knew back in 1996 that there was a risk of airborne contamination through use of the Bair Hugger.

JUDGE LEARY: Was that when Dr. Augustine was still involved with Arizant?

MS. CONLIN: He would have been at that time. And what I'm referring to and I'll show you, Judge, is basically the statements made to the FDA at the time that the 505 was being approved and put on the market.

JUDGE LEARY: So when you're critical of this aspect of 3M and Arizant's performance, you are now talking about a point in time in which Dr. Augustine was directing that program, is that correct?

MS. CONLIN: I am, Your Honor.

And it's ironic that, you know, for the purposes of saying Bair Hugger is safe, they want to rely on the work that was done by Dr. Augustine in the 1990s, but when Dr. Augustine determined after further review it wasn't safe, they're trying to say that you shouldn't rely on that. In our mind, we are not relying on what Dr. Augustine has said. What we're relying on are the statements by Arizant and 3M and what was told to the FDA, and I'll show you that.

They failed to heed recommendations to conduct studies. I'm going to show you evidence by Dr. Sessler, who's a key opinion leader for 3M and on their advisory board. He was begging them for years to do studies and they refused.

We've got manipulation of studies for commercial gain. I'm going to show you some of the evidence by Dr. -- the Sessler/Olmsted article, which was research conducted by 3M, edited by 3M, and their names were added to the publication as part of a legal strategy, their words, not ours.

And then minimizing the contrary evidence. As every single study -- just like in ***Prempro*** and the other cases -- as every study came out, rather than look at and ascertain whether that study was real and posed a real risk, all of the internal documents show -- sometimes before the

study was even published -- that the intent was to go after the authors, to go after the study, rather than look at whether it was actually a legitimate study or not.

So I want to start -- and this goes to your point, Judge Leary.

In 1996 when the 505 -- that's the earlier version of Bair Hugger -- was going through the approval process at the FDA under a 510(k), which just means they have to show it's substantially equivalent to a prior device, they actually raised this issue with the FDA. They said:

"Contamination. Airborne contamination from air blown intraoperatively across the surgical wound may result in airborne contamination," and then they cite two ways to mitigate it. One is a tape barrier which, by the way, 3M doesn't tell doctors that they have to tape or how to tape or a proper procedure for taping, and in fact they've got an underbody blanket that they promote for use in all surgeries which basically lays across the operating table, patient goes on top of it and the air blows up, and it actually is a problem. I'll show you why.

But then they cite two studies. Oh, and then they say the air is filtered through a .2 micron filter.

One of the things and one of the most important buckets of evidence in connection with this is this:

What happened was -- and it's laid out in

Dr. David's report, but basically, the filtration efficiency originally in the 505 was about 93 percent. And by 93 percent filtration efficiency, it means that as air flows through that filter, it captures about 93 percent of the particles, okay? A HEPA filter captures about 99.97. So even this .2 micron filter in the 505 was orders of magnitude less efficient in capturing particulates going through. But here's what happened.

When they went to introduce or get approval on the 750, they first told the FDA they were going to use a HEPA filter. Then afterwards they decided they weren't going to use a HEPA filter and they went back to the FDA in June of 2000 and they said: We're not going to use a HEPA filter, but we're going to use a filter that has the same filtration efficiency as the 505. That wasn't true and it was never true.

The filtration efficiency of the M20, which is the filter that was used in the 750 when it came out, had an efficiency rating of between 50 and 63 percent, meaning that as that air passes through, the bugs are scooped up off of the floor through the intake valve. Upwards of 40 percent of those can go through. Nowhere between 2000 when they put the 750 on the market and 2016 did 3M or Arizant ever do any testing to ascertain what the filter efficiency was of the M20. They went out and they said that's a high-efficiency

filter, it screens out most of the microbes, but that in fact is belied by the documents, which show they didn't do the work.

If you look at --

JUDGE LEARY: When did Dr. Augustine leave Arizant/3M?

MS. CONLIN: I want to say 2003 or 2002.

JUDGE LEARY: Thank you.

MS. CONLIN: Then if you take a look at slide 7 on filtration efficiency -- well, first let's go to this on PX 10.

Customers would call in from time to time and they'd say, "What's the filter efficiency on your devices?" And you can see that even in 2008 they still hadn't done any testing on the M20, which they were using now at this point in time both in connection with the Model 505 and the 750.

In the third paragraph down:

"The filter uses Porous Media's M20 grade. We do not have a published efficiency at .2 micron with this media," meaning the filter media, "but expect it to be significantly lower than 93 percent."

Meanwhile -- this is eight years later -- Arizant is saying: "Hey, we've got a high-efficiency filter."

If you look at an e-mail in 2007 -- I'm sorry, 2013 -- this is 13 years later after the product went on the

market -- they had a question from a customer about is it a HEPA filter, does it clean out 99.97 percent, and they respond with this:

"After much discussion here in R&D, here is our response to [the question]:

"We have no documentation in regards to our 750 [and] 775 filter efficiency."

This is 13 years after they put it out on the market and they told everyone that it adequately screens for particles and bugs "and likely will not aim to obtain this. We cannot claim HEPA efficiency .... All we can do is stick by our claim/statement of high efficiency."

They were saying that without even knowing whether it was true or not, and the record is replete with those types of statements.

Another one. Gary Hansen to Mark Scott, both directors, high-level officials in the company:

"Mark" -- this is in 2012 -- "We do not want to disclose the actual filtration level, but it's sub-HEPA."

And then he says here's the talking points if they push you on what the filtration efficiency is. And again, just simply refusing to look at the issue, and this is against a backdrop of a lot of outside discussion on it.

So if you look at -- what happened was, in 2013, Reed and others introduced, published a peer-reviewed

article that basically said the old filters in the old 505 had an efficiency rating or filter efficiency rating of 93.8, but in the new one it was 61.3. So 3M didn't do the testing, but outside researchers did.

And what happened was, internally at 3M, they started to talk about this Reed article. So in August of 2013, Al Van Duren -- you can see the "from Al V." -- says:

"The assertion that [the] old filters are more efficient tha[n] newer ones is correct. The change to new filter material was dictated by engineering concerns prior to widespread appreciation of the importance of particulates discharged by the warming unit."

So this -- and notice he uses the word "widespread." So in other words, although people who were studying it knew it was a problem, orthopedic surgeons and others are understanding at this point in time in 2013 that it matters. It matters that particles are getting through that filter and into the surgical site. Then in red, Michelle Hulse-Stevens, who's their head director, says:

"This implies then that the 750 does not have a filtration efficiency that adequately mitigates particulates in the air coming out after filtration."

2013. They didn't do anything, they never told anyone. They stuck with their: Just say it's a

high-efficiency filter.

MAGISTRATE JUDGE NOEL: Does the phrase "high efficiency" have any meaning in the industry or in the field of science that we're talking about?

MS. CONLIN: It's not uniform, but I will tell you that what we've been told and what folks out in the field say is people think of high efficiency as being equivalent to HEPA, okay, and of course it wasn't. It was a very low-efficiency filter.

And they misled customers. So look at this. This is a letter, a "Dear Customer" letter in November of 2006, and this was actually after an article came out by Bernards that said: We had an Acinetobacter infection in our hospital. We found it in the Bair Hugger, they found it in another machine as well in the OR, and they switched it out. So Al Van Duren writes on here, you know, the hose isn't sterile. "None of the materials used in the warming hose ... support the growth of any known bacteria."

They hadn't done any testing at that point to say that.

"During use, the temperature and humidity conditions within the warming hose are extremely inhospitable to most microorganisms, as well."

They hadn't done any testing at this point to ascertain whether that was true or not. And:

"The warming unit air filter prevents aspiration of the vast majority of infectious agents."

They didn't even know when they sent this out to customers what the filtration efficiency of their machines were. It hadn't been tested. And as we found out in 2013 when Reed and others did the work, it was about 63 percent. They never warned. They never went back and told anyone about that.

So you don't have to take my word. Here's Al Van Duren, who testified as their 30(b)(6) witness:

"3M is not disputing that the Bair Hugger blower and hose can harbor bacteria inside the device."

We're not disputing that.

They did -- as part of Project Ducky, they did -- and looked at can we coat the inside of the machines with antimicrobial wash? Can we put a filter at the end of the hose to prevent particulates from getting out of the hose and into the surgical area? That was all abandoned, I think, around the time that 3M acquired Arizant. But Project Ducky asked the questions back then: How much bacteria can be allowed to pass through the filter? How much is dangerous? These are questions being asked by people at the time and none of those questions were answered.

Michelle Hulse-Stevens, the top executive in

connection with this unit that the Bair Hugger is marketed out of, in 2013 goes to a forced-air warming aerobiology and orthopedic surgeon convention on prosthetic joint infections. She said she sat in. She says:

"There is amazing concern about any particulates in the air during joint replacement surgery and almost uniform comment that [forced-air warming] increases particulates in the air."

This is 2013. 3M has still never acknowledged this publicly, has never written a letter, has never warned orthopedic surgeons about this, even though their key director knows back in 2013 that this is a problem and orthopedic surgeons are very concerned about it, understandably. It only takes one or two bugs to land on that implant during the surgery to create an infection.

She goes on to say:

"They equate particulates with bacteria in the air and cite studies (do not have the citations)" -- I assume it means she didn't have the citations -- "that support this."

But 3M knows what studies are out there that say if you've got more particulates circulating in the air in the OR, it is a reasonable approximation for the bioburden in the OR.

This is an e-mail between Gary Hansen and Russ Olmsted, who was another one of 3M's -- Russ Olmsted,

another one of 3M's outside advisors, and he brings the Stocks paper to Gary Hansen's attention again in 2010.

And if you look down at the last paragraph -- you know, first of all, he says he thinks the methods in the Stocks paper are very good and he likes the use of electronic particle counts and bacteria air sampling. But then he says:

"For the one investigation I did, I used electronic particle counts and it appears this group was able to demonstrate particle counts serve as a reasonable surrogate for bioburden of air in an OR," which is actually what Michelle Hulse-Stevens also learned three years later.

They've never warned of this. Al Van Duren admitted as a corporate representative for 3M that every single study that exists today shows that the particulate counts in the OR are increased when the Bair Hugger is used. They can get up and argue all they want about, well, we don't think this study says this or that.

Their 30(b)(6) corporate representative says that every single study shows that when you use the Bair Hugger, it increases particulate counts.

They never warned orthopedic surgeons about perhaps not using these. They never warned orthopedic surgeons that the filter wasn't high efficiency or that they had no idea to even tell someone what the efficiency rating

was. Their entire structure and their entire response to all of this is, this is just more Augustine, another article. And that's exactly, if you look at the ***Prempro*** case, the type of evidence that gives rise to a punitive damages claim.

He admitted that they never warned orthopedic surgeons about the increased particle count. They never told customers what the actual filtration efficiency was. They never warned about the fact that their filter wasn't adequate or not high efficiency, and they basically said use Bair Hugger in every surgery, Bair Hugger for everyone.

They didn't do any testing. Aside from warning -- I mean, they admit they didn't have any warning about the risk of airborne contamination in the 700 and they never warned in connection with the 750.

So in other words, back in 1996 they told the FDA: We think airborne contamination is a risk, but they never carried those warnings or put those warnings on either the 700 or the 500 series, and we know why. Because if you told orthopedic surgeons that if you use the Bair Hugger during orthopedic surgery and you're going to have exponentially more particles circulating around the surgical site, people probably wouldn't use it. And we submitted the expert reports both of Dr. Elghobashi, Mr. Buck, and others who have done the testing and said it is exponentially more

problematic with the Bair Hugger on in terms of particulates or bacteria circulating over that site.

JUDGE LEARY: Doesn't the point that a forced-air warming system increases particle counts, doesn't it still beg the question as to whether or not that increases the risk of infection?

MS. CONLIN: No, and that's why I was showing you both the Stocks paper -- and you can see it in both Dr. Jarvis' and Dr. Samat's report, and as well as Michelle Hulse-Stevens. The consensus is that particulate counts around the surgical site is a reasonable proxy for bacteria or bioburden. That's what the Stocks article says, it's in our expert reports, but that's also in the e-mail I just showed you from Gary Hansen and Russ Olmsted.

JUDGE LEARY: But it does still strike me, regardless -- and I don't profess to know any more than what I'm hearing about this. But it does strike me that -- let's say you're talking about a knee and the operative site around a knee. That is well covered with antibiotics at the time of the surgery. So let's say you have increased airborne particles and that may be a conduit for bacteria, but that doesn't necessarily answer the question as given the state of the surgical site with regard to intraoperative antibiotics that that increases the risk of infections.

MS. CONLIN: Well, you can look at Dr. Jarvis'

report and Dr. Samat's report and that, but absolutely it does. Because you can give antibiotics to a patient, you can clean the outside, but when you're placing that implant in the actual area, all it takes is a couple of bugs to land on that implant as it goes in, and because it's a foreign body, you don't have the ability to get rid of it like you would if it was an appendectomy. That's why in orthopedic surgeries the issue of how clean the room needs to be is really important, but --

JUDGE LEARY: How do you distinguish between a bacteria that might have entered the surgical site as a result of forced-air warming from bacteria that might have entered for other reasons? And we know that that exists because it has existed before the use of a forced-air warming device.

MS. CONLIN: And I would point you to Dr. Said Elghobashi's CFD analysis which is part of our submission. He's one of the top CFD experts in the world. And he has shown through his analysis that as soon as you turn that machine on, it is creating turbulent air flow in the OR and is actually creating a current which is pulling up dirty air from --

JUDGE LEARY: I understand all of that, but my question is: When you have a surgical site that becomes infected with bacteria, how does one draw the conclusion

that that bacteria was the result of forced-air warming as opposed to any other possibility for introduction of that bacteria?

MS. CONLIN: Well, I mean, it's twofold. One is that the CFD analysis shows us that when you're in a unidirectional operating room, the particles and the bugs quite correctly stay below the surgical table, go out, all right?

The second thing I'd say to you is, you know that with a PJI you got it during the surgery because it's landed on the implant. You're closed up. It's not like you can assume that there was some sort of, like, changing the bandages or whatever. These infections occurred during the surgery because something has landed on the actual implant.

JUDGE LEARY: My question, though, is, how do you know the source?

MS. CONLIN: And I'm going there next, Your Honor.

The McGovern study, in hip -- in the implants, a randomized study of 1500 people. They found that when Bair Hugger was used it increased the chance of infection -- or increased infection rates by 3.8 times. That under any law anywhere is sufficient to show it's a substantial contributing cause.

JUDGE LEARY: So you believe that the evidence that you've discussed so far and other evidence that you

will discuss constitutes clear and convincing evidence of a deliberate disregard --

MS. CONLIN: I do, Your Honor.

JUDGE LEARY: -- is that correct?

MS. CONLIN: Right.

JUDGE LEARY: And assuming that, then why has there never been a recall with regard to the Bair Hugger?

MS. CONLIN: Well, I'll tell you what my belief of it is. As these infections and issues have come up, they have had, I would argue, a dishonest but very effective campaign to say every time a study comes out -- you can see their internal documents -- you know, argue this, argue that, argue this. Argue that particulates isn't equivalent to bacteria, which we know they know is not true, but that was some of their talking points.

The other thing --

JUDGE LEARY: Let me interrupt. It's concerning to me that it seems that you concede the point that if it is a dangerous product that is otherwise subject to government approval, that the Government hasn't withdrawn its approval because essentially they've been hoodwinked by 3M. I think that kind of argument also begs the question of, well, what is the value of the FDA or any other governmental authority in vetting medical devices if your argument is basically any manufacturer of those devices could hoodwink the Government?

MS. CONLIN: The FDA, particularly with respect to Class II devices -- and keep in mind these were devices where they basically start out saying it's a substantial equivalent to something that's on the market. And as we point out in our brief, the original substantial equivalent was something from 1938 that was used for --

JUDGE LEARY: I want you to get back to my question, though, with regard to why there hasn't been a recall.

MS. CONLIN: Well, and my point is there may be one coming. So one of the things that we showed you was where they're going with the warming/cooling units and the fact that they have figured out that pathogens from that machine can be aerosolized and create infections in the OR. The FDA -- and you can look on the website -- they've started talking about Bair Hugger is part of that same problem, and there's been some on the panel that said: We think Bair Hugger causes infections in cardiac patients.

So you can't assume that because there hasn't been something that the evidence isn't there. We believe that this case was the reason that some of these things are happening. And all of the information that we've got, nobody else has seen.

JUDGE LEARY: Well, it may be that the FDA has done nothing because there's -- a large number of studies

indicate that there's no causal relationship between Bair Hugger and risk of infection.

MS. CONLIN: And that's going to be an argument at trial. Our position is -- and we've got one of the leading epidemiologists in the world that has looked at this, analyzed the evidence under the Bradford Hill criteria, and determined that both -- I mean, one of the things that 3M has been saying is the McGovern study was just Augustine. That's not true.

JUDGE LEARY: Okay. I'll let you move on. I don't want to exhaust any more court time over this issue. I just want to express my questions.

MS. CONLIN: And the only study that's actually looked at this thoroughly has found a three-point times rate of infection when the Bair Hugger is used versus a nonforced-air warming method of warming a patient.

JUDGE LEARY: I'm sorry. Which study is that?

MS. CONLIN: That's the McGovern study, Your Honor. And we've got people on that study like Dr. Belani, who's chief anesthesiologist at the U of M; Mark Albrecht, who's one of the leading statisticians in the case. And Yuri Rekine (ph) stated, said, "Oh, it's just an Augustine study." All these authors have been deposed. All the evidence and underlying raw data from McGovern has been produced to us. Dr. McGovern was deposed for two days and

he stands behind it. We've had an epidemiologist, Dr. Samet, look at it, look at all the evidence, all the underlying raw data that hasn't been made available to anyone, and he says it's absolutely a valid study.

JUDGE LEARY: Let's see if we can be clear about that. You mentioned the University of Minnesota and Mark Albrecht. The University of Minnesota, particularly with regard to its engineering medical devices, was a department with which Dr. Augustine worked, is that correct?

MS. CONLIN: There is some affiliation there, but --

JUDGE LEARY: And also Mr. Albrecht worked with 3M for a period of time and then with Dr. Augustine's own company. And if I recall the testimony of Mr. Albrecht, he very directly said Scott Augustine -- and I think that this may very well implicate the McGovern study, which I haven't read and I will -- that Albrecht expressed the opinion that Augustine thought there was a relationship between forced-air warming and increased risk of infection, and Albrecht commented: But that's the difference between research and marketing, and he dismissed Dr. Augustine's conclusion. And Mr. Albrecht himself, getting back directly to your reference to him with regard to the McGovern study, says there is no causal connection.

MS. CONLIN: Well, keep in mind causal connection

written in that study is in connection with a U.K. doctor. There is a different issue between what a scientist might say causal connection is and epidemiology and research that supports a finding of a substantial contributing cause under Minnesota law.

JUDGE LEARY: My only point is this: Mr. Albrecht was part of that very same process that relates to the McGovern study, and he said -- and he seemed to be -- it's my assumption he was familiar with the research and he says there's no connection.

MS. CONLIN: He didn't say there was no -- I would beg to differ with that. That's not what he said. What they said was it was a 3.8 increased risk, which under Minnesota law is a substantial contributing factor under any case.

JUDGE LEARY: Well, this is what Mr. Albrecht said:

"Unfortunately, Scott likes to say that he's convinced of such a relationship, even though I tell him it is unsupported and I do not agree. Well, that is the difference between research and marketing," end quote.

That's what he said.

MS. CONLIN: Well, I mean, we've cited other portions in the Albrecht deposition, but it's very clear that he stands behind that 3.8 increased risk. I mean,

that'll be an issue, Your Honor. 3M has indicated that they plan on bringing a ***Daubert*** motion on Dr. Samet and Dr. Jarvis, but the evidence is very clear that there is a problem with using Bair Hugger, particularly --

JUDGE LEARY: My only point is this, Ms. Conlin: The standard at least as applies in Minnesota again relates to clear and convincing evidence, and it has to be clear and convincing. The plaintiffs only have to make a *prima facie* showing of that, but a *prima facie* showing of clear and convincing evidence. And when you cite the McGovern study for a particular proposition and you cite Mr. Albrecht as essentially vouching for that, that's what makes me concerned about that piece of the argument, because I think I need to focus on the clear and convincing evidence that you have, and clear and convincing should not be subject to a lawyer's interpretation.

MS. CONLIN: Well, I would agree with that if we were making a decision today on whether we can succeed in front of a jury on punitive damages. For the purposes of making an amendment on a *prima facie* case, the evidence goes in unrebutted. And we'll have Mark Albrecht at trial, we'll have Dr. Belani at trial. We will have these people that will testify.

JUDGE LEARY: I'm not talking about rebuttal. I'm talking about the argument that's being made on behalf of

plaintiffs who claim that there's clear and convincing evidence of a deliberate disregard for the rights and safety of individuals. That's what I'm saying. And you're relying on the evidence -- strike that -- you're relying on certain research, but you're also interpreting that research and whether or not you're accurately interpreting that research, that is an issue for consideration.

MS. CONLIN: Well, and that's why we put in the full reports of Dr. Jarvis and Dr. Samet, who have opined to a reasonable degree of scientific certainty based on their years of work in infectious disease and epidemiology that there is a causal link. And they looked at, by the way, a lot more evidence. I mean, you asked me about the FDA.

JUDGE LEARY: I don't want to go there. I'm just talking about McGovern. I'm talking about the McGovern report and how you characterize it. That's what I'm concerned about. Again, I haven't read it, so, you know, maybe the gloss that you put on is absolutely accurate, but it has to be accurate and it cannot be subject to a gloss that a lawyer puts on it that otherwise isn't contained within the article. That's all I'm going to say about it.

MS. CONLIN: And I hear you and I would just direct you back to those reports that were submitted in their entirety.

The other thing I would tell you is, our claim for

punitive damages and a *prima facie* showing of a deliberate disregard to the rights and safety of others is not just premised on McGovern. It's premised on the fact that they changed the filter, never told the FDA. I mean, Dr. David says --

JUDGE LEARY: I've heard that part of it.

MS. CONLIN: Okay.

JUDGE LEARY: If you told something new, I'd be interested in it, but I've heard that part.

MS. CONLIN: So one of the things that 3M says in their brief is no doctor or healthcare provider has ever reported that the Bair Hugger system caused one of their patients to develop a surgical site infection.

In point of fact, if they're saying that Jane Doe was injured on June 6th through the Bair Hugger, if that's what they're talking about, that's true, but there's all sorts of internal documents, this one in particular, where they had people writing them from the field. They said Dr. Bratzer won't use the Bair Hugger because he thinks -- "Their position is that they contribute to post-op wound infections because of the circulating air (air turbulence, et cetera)."

And 3M writes to Mark Scott, who's head of the group, and says: "This issue is everywhere. We have got to develop a better strategy besides the Zink article." That

was the article from Augustine in 1996. That was the one that 3M had been writing. And this is all the way up to 2010. They had numerous orthopedic surgeons contact the company, both at Arizant and 3M -- this is just one example -- and say: We think Bair Hugger is creating post-surgical prosthetic joint infections. We're not going to use it anymore.

And in fact, people would say: What is the filter efficiency? They'd say: Just tell them it's high efficiency. And that went on over and over again.

Some people wrote in to them and said: Hey, we've had an Acinetobacter outbreak at the hospital. What do we do? 3M would quietly tell them -- or Arizant before 3M -- that they would remove and discard the filter and deposit it in biohazardous waste. They only told that to people if they were calling in. They never told anyone that the filter could be a problem and that you need to change it if you've had an outbreak at the hospital. They never did it. This is the same Al Van Duren who signed the "Dear Valued Customer" letter in 2006 saying: Don't worry about it. Our filter is really good.

And at this point in time they hadn't done any testing. They never studied. They never did any validation tests on the 750. They never did any testing to see whether anything that they were doing would prevent airborne

contamination.

Same thing on the 505. They never did any validation. They never did any biological testing. They never did any airborne particulate testing, none. And they never did any testing on the filter either. They put it out into the marketplace, and as the evidence, you know, basically accumulated, they stayed on the same path.

Michelle Hulse-Stevens' deposition this year, you know, that -- basically saying, you know, there's "types of studies that you believe provide adequate evidence for the adoption of particular interventions which could be less difficult to conduct" rather than a randomized trial. And she agrees one of them would be an aerobiology study and it hasn't been conducted. And she goes on to admit that that decision was made at the highest levels of the company.

The reason why they didn't want to do it -- and you've seen this document before, the war games and the nightmare scenario -- they were concerned about someone doing a study. So rather than go forward and do an appropriate study if they wanted to, you know, claim that this wasn't a problem, they had the areas of concern in front of them, a definitive study showing forced-air warming as a source of SSI. Someone does a study on forced-air warming and contamination, a study on forced-air warming versus HotDog in orthopedics.

And you had the FDA come and inspect at Arizant in 2009 and came up with -- or believed when they left, probably because of the high-efficiency -- and that goes to the point you were asking me about: Does high efficiency equate with HEPA in the minds of people in the field? Yes. Clearly it did here, because the FDA thought that they had a HEPA filter on their device. That wasn't corrected until December 1st of last year, 2016, 16 years after it went on the market.

And what's interesting is, they want to correct that misimpression from the FDA in 2009, so six years later, seven years later, and apparently they think it's so urgent that they sent it via e-mail and overnight delivery, and they claim they just recently realized it when in fact that was pointed out to them at the outset of the litigation in Texas.

And so they hadn't done any verification testing on their filter until 2016, and they never told the public.

Reluctance to study, another example of what can give rise to a *prima facie* case of punitive damages.

ECRI wanted to do -- an outside group wanted to do a study. First thing they say is: "Our first step with ECRI should be preventing them from doing their own testing, but rather to rely on published data."

If you look midway down, some of the talking

points: "The Albrecht paper does not actually measure [colony forming units] CFUs, but rather leads the user to conflate particles with germs." They knew that's a reasonable proximation, but these are their talking points in response to people wanting to do a study.

JUDGE LEARY: Isn't that a risk, that a person might conflate particles with germs in coming to a decision as to whether or not there's a risk?

MS. CONLIN: The way I read it was that this was a reason to tell ECRI not to -- to dismiss the Albrecht paper because it was dealing with particulates rather than germs. But as you've seen from the other documents, they know and have known since the Stocks paper and others came out years and years earlier that it is a reasonable -- particulates is a reasonable equivalent for bacteria.

Dan Sessler, one of their -- a doctor, one of their outside experts, 2011, says we got to do a study. We have to do a study. "Waiting much longer seems like a dangerous strategy." Michelle Hulse-Stevens weighs in not on this, but in the same time frame, and says: We're not going to go forward with any study.

"However, with the Legg study, and the limitations of the Sessler study, before we proceed with any further engagement it would be helpful for Carol and I to have the opportuntiy to meet with the core stakeholders on the

strategy here to make sure we are fully informed ...."

And you saw from her deposition testimony they made the decision at the highest levels of the company not to do any testing.

Dan Sessler, Dr. Sessler, again in response to criticisms of the Sessler/Olmsted study they had just published, writes to Gary Hansen. He says:

"I'm pretty unhappy. I took this project on as a favor and it has ended up costing a huge amount of time ... [and] may damage my reputation.

Then he says:

"This was completely preventable. As I've been saying for a year, only a bacterial sampling study will adequately deal with this issue."

And we know that they didn't do anything.

Now, why would Dan Sessler, Dr. Sessler, a 3M key opinion leader and someone who's on their medical advisory board, think doing a bacterial study would be important while 3M at the highest levels was saying don't do it?

This (indicating) is why. Dr. Sessler thought that the air coming out of the Bair Hugger was sterile. He's one of 3M's key opinion leaders. He's on their medical advisory board. He's saying: We've got to do a bacterial sampling. We have to show that this product is safe. 3M at the highest levels of the company said: We are not going to

do it. And the reason why Dan Sessler thought it would be a good study is because he thought the air was sterile.

If people on 3M's medical advisory board and key opinion leaders think that the air coming out of the Bair Hugger is sterile, can you imagine what people out in the field think and orthopedic surgeons who aren't enmeshed and do have access to all these internal studies? That's the problem. Everybody thinks the air is sterile and I think the FDA thinks that too. They never told the FDA that they had changed their filter. They haven't told the FDA about the number of pathogens that have been cultured in the machines and people have called in and said: We've got problems. They haven't told the FDA about the Acinetobacter outbreak in Kentucky where they changed the filter in the Bair Hugger and it stopped. They haven't told the FDA any of that.

And on a Class II device, the FDA relies on the manufacturer to do the right thing. It's not like a Class III drug, that it's gone through and there's clinical trials. The FDA gets what you get. And there was never a letter to file done when they changed the filter out, any of the steps -- and you can see it in Dr. David's report -- any of the steps a reasonable manufacturer would have done and should have done in connection with this.

So finally, you know, again, just another example

of the reluctance to study. And in fact, in this document they're basically referencing one of the reasons they were not doing it is because of the ongoing legal situation.

And then I want to talk just briefly --

JUDGE LEARY: Let me stop you there, Ms. Conlin.

MS. CONLIN: Yes.

JUDGE LEARY: Just a point of clarification.

With regard to slide 53, the Sessler letter to Hansen, there's a reference --

MS. CONLIN: I'm sorry. Which slide, Your Honor?

JUDGE LEARY: 53.

MS. CONLIN: Slide 53?

JUDGE LEARY: And it's a Sessler letter to Hansen. Sessler says to Hansen at the end of the first full paragraph: "[J]ust the fact that a complaint was filed already has to some extent."

What is the complaint there he's referencing?

MS. CONLIN: So there was -- after the Sessler/Olmsted study was published -- and it had problems with it, and even 3M internally says it's got some problems with it.

It was a study that basically Gary Hansen did, and then as part of their legal strategy -- and we put it in the documents that we submitted -- added -- got Sessler, Dr. Sessler and Russ Olmsted to be the authors even though

they didn't do any of the work. And people had issues with how it was done, what the reporting was, and I'll explain --

JUDGE LEARY: And my question was, what is the complaint --

MS. CONLIN: So the complaint was that the data that's presented in the paper is misleading, essentially.

JUDGE LEARY: Who made the complaint and to whom?

MS. CONLIN: It was -- I'd have to pull that out, Your Honor.

JUDGE LEARY: If you don't know, that's fine.

MS. CONLIN: I did know at one point when I took Dr. Sessler's depo, but I don't. But anyway -- so he didn't know the answers to the questions that were coming in and therefore, you know, went on to 3M.

So the Sessler/Olmsted study was basically saying that you can use the Bair Hugger in a laminar flow operating room, what's known in the U.K. or Europe as a DIN, and that even with the Bair Hugger on, you still meet these DIN standards.

One of the things that happened in connection with this study is that one of the study sites at Amersfoort where an underbody blanket was used, they found a five to tenfold increase in particulates over the surgical site, which is statistically significant. And so what they talked about was combining that data and averaging that data with

the other sites so that it wouldn't be statistically significant.

And, you know, basically you've got Dan Sessler writing to Gary Hansen, who did the study, the 3M employee, and it says: "The increase with the 635 cover on ambient or warm in Amersfoort seems substantial, roughly a factor of five to ten." It goes on: "What clinicians will want to see is basically particle counts under the three test circumstances .... Any substantial increase will concern them and basically validate Scott's point that forced-air warming increases risk."

And they had the data. They had the data as a result of this. And what they did was, they not only moved Amersfoort into basically an amalgamation of all the sites, but they -- if you look at the next slide, they actually deleted from the text of the study, which was -- this is part of the draft -- "The significantly higher counts seen with the blanket model 635 reflected conditions at [operating room] Amersfoort." They deleted that. The reason why they deleted that is because they know that if anybody understands that the use of the Bair Hugger increases the particulate counts around the surgical site, they will have a problem with it, or to quote Dr. Sessler, "Any substantial increase will concern them." And so that was deleted from it.

And again, straight out of the cases from ***Mirapex*** to ***Levaquin*** to ***Prempro*** where you are manipulating scientific data for your own commercial gain, that is *prima facie* evidence of a punitive damages claim.

So finally we have this, and you saw what 3M's reply to it was, but it was talking points on forced-air warming and SSI prevention. "June 2010, Our position.

"There is no evidence that forced-air warming increases surgical site infections."

Al Van Duren weighs in and says: "Actually, there is evidence that [forced-air warming] use increases risk -- This evidence was the motivation for Dr. Memarzadeh's work," and that was a guy who did an unpublished study.

So they've tried to spin it in their brief. They've tried to say, well, that's not what he meant. He made a careless mistake. But you can't look at their spin on this for the purposes of ascertaining whether we've met our *prima facie* case.

So we've showed they failed to warn about the risks. They failed to warn that their filter -- they had changed their filter. They had failed to even test whether they had an efficient filter. They failed to warn about the risks in increased particulate counts in orthopedic surgeries. They failed to study the risks. They had people saying we should do this and at the highest levels of the

company they decided not to. They failed to heed recommendations by people all over the place saying we should do a study, and of course those people thought the air out of the Bair Hugger was sterile. They didn't provide any information to the FDA that they had changed their filter media and now they had an efficiency of only 63 percent, meaning that 40 percent of whatever gets sucked up off that floor is going through that. They manipulated the Sessler and Olmsted study for commercial gain and in fact added them as part of their legal strategy.

And they basically -- and it gets to the point you made, Judge, which is, they have worked assiduously hard to tamp down any legitimate scientific inquiry into this, and the FDA and others -- you know, the shoe hasn't dropped yet, but they're talking about the Bair Hugger like they are talking about the warming/cooling units, and we've got the expert reports that demonstrate and show by top scientists in the world that what I presented today is true.

MAGISTRATE JUDGE NOEL: Let me just ask this question: I understand that we're only looking at the *prima facie* evidence and the evidence that you present to determine if it -- whether it is clear and convincing evidence of a deliberate disregard, but your evidence itself are these studies, correct, some of your evidence?

MS. CONLIN: Some of our evidence is the studies

themselves as well as our expert reports which are based on additional underlying data from the studies that was produced in discovery and reviewed by our experts.

MAGISTRATE JUDGE NOEL: Okay. And then how do you address the table that the defendants have in their brief at pages 7 and 8 where they list -- go through all the studies and quote from them that the study did not evaluate the link between forced-air warming and surgical site infection, or do not establish a direct --

MS. CONLIN: I mean, I would just go back to the fact that our experts have looked at all of that. There is a difference between what an author may conclude in a study and what the actual data shows. But, you know, in the ***Mirapex*** case in front of Your Honor, the defendants asserted there had been no evidence of a cause-and-effect relationship between ***Mirapex*** use and pathological gambling. Same thing. There wasn't a study that said absolutely there is a definitive causal link. It was accumulation of evidence just like here. And, you know, basically they said that scientific evidence to date has shown merely an association between ***Mirapex*** and impulse disorders.

And that was sufficient based on the cumulative evidence to say a jury may not agree with us, but we've certainly presented enough evidence to meet the *prima facie* showing, which is unrebutted. You can't make credibility

determinations. They can put Al Van Duren on the stand and he can say, you know, "I didn't mean what I said," but a jury under these cases is entitled to take a different view of it, and that's consistent with ***Levaquin*** as well.

MAGISTRATE JUDGE NOEL: Okay. Thank you very much.

MR. BLACKWELL: Your Honor, Mr. Hulse will be arguing.

MAGISTRATE JUDGE NOEL: Okay. All right.

MR. HULSE: We've been going for awhile. If either of Your Honors wants to take a short break, or otherwise I'll proceed.

MAGISTRATE JUDGE NOEL: I think the more important question is whether Tim needs a quick break.

(Discussion off the record between Judge Noel and the court reporter)

MAGISTRATE JUDGE NOEL: We'll take ten minutes and we'll be back.

(Recess taken at 10:40 a.m.)

* * * *

(10:50 a.m.)

IN OPEN COURT

MAGISTRATE JUDGE NOEL: Good morning. Please be seated.

Mr. Hulse?

MR. HULSE: Good morning again, Your Honors, Judge Noel, Judge Leary. Ben Hulse for the defendants.

I'd like to before I get into the meat just address some of Judge Leary's questions from the last session.

MAGISTRATE JUDGE NOEL: I'm sorry. Before you start --

MR. HULSE: Of course.

MAGISTRATE JUDGE NOEL: Judge Leary and I both have a concern about timing. How much time do you think you're going to be going?

MR. HULSE: Fifteen minutes.

JUDGE LEARY: How long?

MR. HULSE: Fifteen minutes.

JUDGE LEARY: Fifteen.

MR. HULSE: Yes.

MAGISTRATE JUDGE NOEL: Okay. You're up.

JUDGE LEARY: You're on the clock.

MR. HULSE: Thank you, Your Honors. I think I can be quick.

Judge Leary asked who that complaint that was referred to by Dr. Sessler came from in 2010, and as we pointed out in our brief, that complaint came from Dr. Scott Augustine. That was the complaint that Counsel couldn't recall.

And I also wanted to note that, of course, as has been mentioned here, there hasn't been an FDA recall warning letter and nor have the plaintiffs put in any evidence of any kind that there is any kind of probability of an FDA action. They mention --

MAGISTRATE JUDGE NOEL: What about this HEPA thing, though? I'm just -- HEPA is an acronym, correct?

MR. HULSE: HEPA is an acronym.

MAGISTRATE JUDGE NOEL: High Efficiency Particle something or other, right?

MR. HULSE: That's right.

MAGISTRATE JUDGE NOEL: So what is the meaning of high efficiency? And it appears that for at least six years the FDA thought you had a HEPA filter.

MR. HULSE: Well, the FDA made a mistake and the plaintiffs don't put in any evidence that anybody from Arizant -- it was Arizant at the time -- ever told anybody at the FDA that it was a HEPA filter. High efficiency is a -- and we've put in the ASHRAE evidence on it -- is a much broader category than just HEPA. Obviously this -- you know, it can lead to some confusion, but the ASHRAE standards are clear. ASHRAE uses a standard called MERV. ASHRAE is the society of engineers that comes up with these standards.

Plaintiffs have said here that we never tested the

filter. Obviously you're not supposed to consider our rebuttal, but when a plaintiff's lawyer makes an argument that something never happened and it did, I think the standards would allow for some rebuttal there.

We did put in the evidence of the testing that occurred on the filter. The filter shows a rating of MERV 14, and MERV 14 is the recommended efficiency standard by ASHRAE, which again is the organization that sets these standards for general surgery in the operating room. It is the same type of efficiency that is used for the hospital filtration system. And I'd add that the Bair Hugger system is the only device in the operating room that includes a filter. The only other filter in the operating room is in the filtration system.

And so like in the ***Beniek*** case, the fact that 3M has added an additional feature to the Bair Hugger system despite the utter lack of scientific evidence of causation of surgical site infections cannot be a basis for punitive damages.

But, Your Honors, just to get back to it, to the FDA, Ms. Conlin made the statement that all the info we've got the FDA hasn't seen. That is, of course, not true. They rely on studies that are fully available to the FDA. The FDA has -- McGovern, of course, is a published study and the FDA has inspection rights and conducts audits and we've

produced the documentation from the audits. There's no secrecy here. And the FDA has conducted no -- there's been no warning letter, no enforcement, and so forth.

The standard here, as Judge Leary has recited, for Minnesota law, to the extent Minnesota law applies to any case, is basically it can't be a close call. There has to be clear and convincing evidence that 3M and Arizant had knowledge of facts or intentionally disregarded facts creating -- and these are words that the plaintiffs never use -- a high probability of injury. That is a standard that doesn't appear in every state's law, a high probability of injury, and then deliberately acted in conscious or intentional disregard of that high probability of injury.

And as was said in the ***Ulrich*** case, the mere existence of negligence or gross negligence doesn't meet the standard.

Another piece of the statute that Plaintiffs don't talk about is Section (c) and (d) of 549.20, which is that acts of employees can only be imputed to 3M and Arizant if they're done by a manager with authority to establish policy and make planning level decisions. That's not more clearly defined, but it implies essentially a C-Suite manager, or an employee whose acts are ratified or approved by a person in that position. And there are multiple cases from the District of Minnesota that deny leave to amend or grant

motions for judgment as a matter of law based on the fact that the plaintiffs haven't provided evidence that the statements or acts by the employee were either by an employee who had managerial authority or were ratified or approved.

And this gets to the heart of it, that we have here a -- snippets from a whole bunch of documents from 3M's internal files, and that what Plaintiffs have done is essentially appended them to each other, welded them together with lawyer argument, to create some kind of a shadow of misconduct. But the statute and the intent of the legislature is clear. This is not about shadows. The misconduct that gives rise to punitive damages should be as obvious as an elephant that's painted fuschia. It should be clear and convincing. And that's -- and this is not a close call here.

MAGISTRATE JUDGE NOEL: I'm sorry. Your metaphor, is that in a case?

(Laughter)

MR. HULSE: I was debating which color to paint the elephant, Your Honor.

So I think, as the Court has deduced, what this really comes down to is the McGovern study. Plaintiffs have to prove that 3M or Arizant had knowledge of facts of a high -- constituting a high probability of injury to the

plaintiffs. Now, we don't concede at all that there is a high probability of injury that's established by the McGovern study, but more to the point is what the McGovern study itself says.

As we point out in the chart that Judge Leary alluded to, every single one of the studies that Plaintiffs rely on and their experts rely on disclaims any finding of causation, but I've pulled out McGovern here specifically. McGovern and his co-authors, including Mark Albrecht, an employee of Scott Augustine, say:

"This study does not establish a causal basis for this association. Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational [only] and may be confounded by other infection control measures instituted by the hospital."

Now, what does observational mean? In scientific research, that means you didn't control. It's a noncontrolled study. And then they give an example:

"For example, changes were made to the antibiotic and thromboprophylaxis protocols used during the study, although no infection controls were made after February 2010."

So in other words, the antibiotic regimen was changed in the midst of the study, and of course the

antibiotic regimen is going to have some significance for the development of surgical site infections. And this is why, as was shown in Mark Albrecht's testimony that Judge Leary was alluding to, it is wrong to draw a causal conclusion from this observational study. And yet Plaintiffs would say, despite the disclaimers in the study itself and the statements of its co-author, Mr. Albrecht, who works for Scott Augustine and has had every incentive in the world to support the boss, they say this is clear and convincing evidence of a deliberate disregard of a high probability of injury to the plaintiffs. It's not a close call.

MAGISTRATE JUDGE NOEL: But isn't this precisely what the statute says we're not supposed to do? In other words, this is rebuttal.

MR. HULSE: No, it's not, Your Honor. It's the plaintiffs' own evidence that's been presented.

MAGISTRATE JUDGE NOEL: Well, the study, and then the evidence is the experts they have who they say they go beyond the study by looking at the data upon which the study is based and reach different conclusions.

MR. HULSE: Indeed. The plaintiffs' experts reach different conclusions than the authors of the studies on which they rely. We agree with that.

I'd say as an initial point that --

MAGISTRATE JUDGE NOEL: But isn't that the evidence that we have to look at? That's the *prima facie* evidence. That's what the plaintiff wants to present to the jury, and now you're going to come in and say, "Well, no, let's look at the study and let's look at what the study authors said, and now I'm going to poke some holes in what your expert says." And all of that is fodder for the issue of whether they get punitive damages, but at this stage, don't we only look at what their expert said?

MR. HULSE: And they have presented these studies and the studies say what the studies say, and that is part of what the Court must weigh in determining whether there is in fact clear and convincing evidence submitted. When those studies that the plaintiffs submit to the Court, which are the same studies their experts are citing, say something that doesn't support the standard, that's something certainly the Court can take into account. That's not our rebuttal. That's just if we didn't say anything at all and I never stood up, the Court would look at those documents and see this.

And also, in terms of the plaintiffs' expert reports, there are -- the two cases out of this district, ***Berczyk*** and ***Healey***, that have addressed whether an expert report can be considered by the court on this motion have both concluded it cannot. Both courts have concluded that

an expert report that is not submitted as an affidavit under oath cannot be considered under the statute.

And these cases aren't hard to find. There are only, you know, about 20 cases total out of the District of Minnesota and the Minnesota state courts about motions for leave to amend, and that's at this point the universal holding, conclusion of the courts about whether you can consider expert reports. And again, all that these expert reports are doing is taking the same evidence and drawing a different conclusion.

And I'd like to add something else. Here's another --

JUDGE LEARY: And Judge Noel's question that the representations by a lawyer what is contained in a report is not the evidence to be considered, but it's rather the report itself --

MR. HULSE: It's neither, Your Honor. Of course, the case law is clear that lawyer representations about the evidence are not to be considered, just the evidence itself, in determining whether the plaintiffs have made a *prima facie* case, but the expert reports are in this sense equivalent to lawyer argument --

JUDGE LEARY: I'm not talking about expert reports. I'm talking about the articles themselves.

MR. HULSE: The articles themselves --

JUDGE LEARY: The calculation as to whether or not the standard that's been met depends on what the articles -- I may have said reports -- what the articles say as to how counsel characterizes it.

MR. HULSE: I couldn't agree more.

JUDGE LEARY: Okay.

MR. HULSE: And here's -- just to get to the heart of it here, the plaintiffs submitted the Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection. This was a gathering in 2013 of 400 of the world's leading experts in surgical site infections, joint infections, from 52 countries. They came together to see whether they could make some consensus statements on issues of SSIs. The plaintiffs put this in, but they omitted a couple pages at the end, and I don't think this is rebuttal, Your Honor, to introduce the pages that they omitted from what they supplied to the Court. This is just principles of evidentiary completeness.

So they submitted these proceedings -- and again, a gathering of 400 of the world's leading experts on surgical site infections, and they looked at the question -- this is in 2013 -- "Do FAW" -- that is, forced-air warming blankets -- "increase the risk of SSI?" -- that's surgical site infections -- and they reached this statement:

"We recognize the theoretical risk posed by

FAW" -- forced-air warming blankets -- "and that no studies have shown an increase in SSI related to the use of these devices. We recommend further study but no change to current practice."

That was agreed upon, that statement, by 89 percent of the attendees representing a strong consensus. Five percent disagreed. We don't know why. But I want to be very clear what they looked at.

They looked at exactly the same studies that the plaintiffs are putting in front of the Court as evidence of deliberate disregard for a high probability of injury. I'm sorry. I wish I could blow this up a little bit more.

But the first reference at the top is the McGovern and Albrecht studies. Also, they cite here the Legg study.

JUDGE LEARY: I assume that the full article is part of the record, and if so, could you cite us to that?

MR. HULSE: Yes, Your Honor. So we submitted the missing pages at Defendant's Exhibit 4, and it was -- I'm sorry -- it was Plaintiff's Exhibit 4, Defendant's Exhibit 18.

JUDGE LEARY: Thank you.

MR. HULSE: Right. And so what Plaintiffs' position is, that a statement here, that no studies -- and that includes McGovern -- have shown an increase in SSI related to the use of forced-air warming devices and

recommending no change to current practice, agreed upon by 89 percent of experts who attend, these 400 experts in orthopedic surgery and surgical site infections, disagreed with by only five percent. What the plaintiffs are saying is that your failure to agree with this five percent is a deliberate disregard of a high probability of injury to Plaintiffs. Again, Your Honors, this isn't a close call.

MAGISTRATE JUDGE NOEL: What was the total universe of attendees at this event?

MR. HULSE: Sure. I'll just pull it right up.

Four hundred delegates from 52 countries and over 160 societies, also referred to here as 400 of the world's experts in musculoskeletal infections from 52 countries.

So what you have here is -- and I understand that the plaintiffs didn't put it into the record, but we did introduce for the Court's potential consideration a number of other studies from respected -- statements from respected independent groups, like the Association of Perioperative Nurses and ECRI, which represents thousands of healthcare providers around the country, all reaching the same conclusion based on review of the plaintiffs' literature.

Back at science day of last year, all that Plaintiffs were able to present is, again, the McGovern study. Today too, a year later after all this discovery, the only thing they can point to -- that they're pointing to

as proof of causation is the McGovern study, but the McGovern study disclaims causation and the community of people in the field overwhelmingly reject exactly the conclusion that the plaintiffs are reaching.

And in order to keep to my 15 minutes, I'm going to proceed just quickly through some other items here.

The plaintiffs rely very heavily on both ***Levaquin*** and ***Mirapex.*** They fail to note that ***Levaquin*** was reversed on punitive damages by the Eighth Circuit. ***Mirapex*** certainly was not.

Unlike -- in ***Mirapex***, Judge Noel, you may recall that the corporate parent of BIPI, the defendant, actually issued a statement on the topic of pathological gambling and whether warnings were needed, and they issued the statement that the data strongly suggests a pharmacodynamic effect of Mirapex on pathological gambling, and then the evidence that the plaintiffs put on was that they repeatedly told the U.S. subsidiary, who was the defendant: You need to warn about this.

In addition, there were clinical trials for years where people developed pathological behavior, clinical trials that were run by the defendants, and then there were multiple reports that came in from doctors saying: Your drug caused compulsive gambling that were then not reported to the FDA. That was the evidence in ***Mirapex***.

We have nothing like that here. We have no statements by 3M or Arizant executives, the people who need to make these kind of statements under the statute, that the Bair Hugger system causes surgical site infections. We don't actually have statements to that effect at all from anybody. And unlike ***Mirapex***, we have no doctors reporting to 3M or Arizant that their patients developed surgical site infections caused by the Bair Hugger system. And I mentioned here just on this piece of paper the ***Healey*** and ***Mack*** cases that are cited in our briefs, both from the District of Minnesota, that denied leave to amend where that evidence was lacking.

The plaintiffs pointed and -- and this was on their slide 21 -- to an e-mail from a hospital to a sales rep at 3M reporting that some orthopedic surgeons are refusing to use forced-air warming devices, and the plaintiffs say: Ah-ha. This is evidence that surgical site infections -- that doctors were complaining about infections caused by the Bair Hugger system.

Well, first off, that's not what the document says. And in fact, what the hospital representative relates is that their concern is based on, quote, literature they have. So based on the record in front of the Court, what is the literature that the doctors would have had on January 20th, 2010? Well, the only thing that was out at

that point was the first Albrecht study from 2009 which, like McGovern, disclaimed any causation. So this evidence of a doctor report that they're pointing you to appears to just be a report that some doctors were concerned based on a study that was authored by an employee of Augustine that disclaimed causation. If they had evidence of a doctor coming to 3M or Arizant and saying, "My patient developed a surgical site infection because of your device," you could be sure you would have heard about it.

MAGISTRATE JUDGE NOEL: So just on that point, who are these folks? Let me start at the bottom.

So Vicki Jones is a hospital person?

MR. HULSE: Yes, a hospital rep at -- yes.

MAGISTRATE JUDGE NOEL: And she's writing to Dr. Bratzer, who is an Arizant person?

MR. HULSE: No.

MAGISTRATE JUDGE NOEL: A 3M person?

MR. HULSE: No. I don't know who Dr. Bratzer is.

MAGISTRATE JUDGE NOEL: Okay.

MR. HULSE: But it clearly is forwarded to a district sales manager at Arizant.

MAGISTRATE JUDGE NOEL: Okay. And then there is the e-mail immediately above that from Suzanne Tullis. Who is she?

MR. HULSE: She is a sales representative for

Arizant.

MAGISTRATE JUDGE NOEL: And who are Mark Scott, Jami Collins, and Julie Wick-Powell?

MR. HULSE: They're marketing employees at Arizant at the time.

MAGISTRATE JUDGE NOEL: And marketing employees meaning, like, just marketing managers?

MR. HULSE: Marketing managers, exactly.

MAGISTRATE JUDGE NOEL: Some high-level executive in the marketing department --

MR. HULSE: No, not executives. I'd add that of course it's Plaintiffs' burden to establish that any of these people -- they call everybody executives in their briefing, but they don't put in evidence that they are.

MAGISTRATE JUDGE NOEL: Okay.

MR. HULSE: The only person I think who might meet that criterion who they quote from is Gary Maharaj, who is the former CEO of Arizant, but all they quote him for is, they said: Do you remember any studies being done during a time period that he wasn't working on the Bair Hugger 505, and he says: I don't recall. So that doesn't seem like clear and convincing evidence of deliberate disregard.

And also, Plaintiffs' cite very heavily to ***Prempro***, the Eighth Circuit decision, their position being like this is just like ***Prempro*** in that there was no research

to back up 3M's claims about the safety of the Bair Hugger device. Well, all you have to do is look to Plaintiffs' brief where they spent pages quibbling with our studies or the citations.

In the studies that they submitted, you just have to go through the references and the dozens of references to see the extensive academic literature that was out there and has been out there and that has only grown that establishes the safety of the device. So the fact that a lawyer argues 3M didn't study, or Arizant didn't study, or there are no tests is not something that the Court can take as evidence, when the evidence in front of the Court, including the evidence submitted by the plaintiffs, is that there's extensive research done that establishes the safety of the Bair Hugger device.

And the bottom line -- and this was the basis -- one of the stated bases of the Eighth Circuit for reversing punitives in ***Prempro*** -- is that there's no dispute that the Bair Hugger system has been used in 200 million surgeries, thousands every day, and remains the standard of care today.

I'd like to just -- I'm probably over 15, but I'd like to talk about choice of law for a few minutes. Choice of law is always a gnarly area.

Judge Noel, in ***Mirapex*** you treated the entire punitives regime as substantive and therefore looked to each

state -- and of course, that was just -- there were 15 bellwethers -- to determine whether a *prima facie* case even needed to be made, and then, of course, looked subsequently to those states for the standard.

Since ***Mirapex***, cases in the District of Minnesota have uniformly concluded that the *prima facie* case requirement is procedural rather than substantive, so that applies no matter what.

However, the actual substantive requirements, like the deliberate disregard standard, is substantive, and so you have to look to the state -- you have to apply choice-of-law principles.

Now, something that got missed in the briefing on both sides -- Plaintiffs don't talk about choice of law at all, but we should have noticed this at the time -- is that the Court actually has an order that speaks to this. This is Pretrial Order Number 5.

And Judge Leary, I won't forget about Ramsey County here, but this is just for the MDL.

And what it said is, with regard to the determination of applicable procedural law for any action directly filed in this district -- most actions are directly filed -- Minnesota's procedural law should apply. So that would proscribe under this order that a procedural requirement like the *prima facie* you have to seek leave to

amend, *prima facie* case, applies to all cases.

But then it goes on to say that for the determination of the applicable substantive law for any action filed in this district -- that is, direct filed -- in the event of a dispute between the parties concerning the applicable substantive law, the Court will apply Minnesota choice-of-law rules unless the plaintiff clearly identifies the following information in the initial complaint: current residence, date and location of surgery, and the appropriate venue where the action would have been filed if direct filing in this district were not available.

And in fact, the short-form complaint that every plaintiff has had to submit provides exactly that information. So what that means is, for all direct-filed plaintiffs, the Court actually has to apply the choice -- in determining the substantive law -- apply the choice of law of whatever venue the case would have been filed in originally.

MAGISTRATE JUDGE NOEL: Which means, just to make sure I'm understanding, even after whatever you say the district has done since ***Mirapex***, any state -- any plaintiff whose case would otherwise have been venued in a state that has no requirement for any pre-plea showing of any kind gets to allege punitive damages right off the bat, correct?

MR. HULSE: The opposite, Your Honor. So it's

actually that everybody has to seek leave to amend regardless of their state. This is the difference from ***Mirapex***.

MAGISTRATE JUDGE NOEL: I'll grant you that.

MR. HULSE: Right.

MAGISTRATE JUDGE NOEL: But then once they make that motion, that motion is granted if their state doesn't have a requirement that there be any heightened level of pre-plea review, correct?

MR. HULSE: No, Your Honor. They have to make a *prima facie* showing that they have met that state's substantive standard.

MAGISTRATE JUDGE NOEL: Right. And if there is no standard in that state --

MR. HULSE: Oh. If there was no standard --

MAGISTRATE JUDGE NOEL: I don't know what any states are. That's why I asked the question. I seem to have this recollection of Florida and whatever one Ms. Conlin mentioned from ***Mirapex***, but I'm assuming there are some states out there that don't have this.

MR. HULSE: Right.

MAGISTRATE JUDGE NOEL: Minnesota appears for whatever reason to sort of been a leader in tort reform back in whatever year this statute was adopted.

MR. HULSE: Right. But today it's sort of middle

of the road, actually. It was an early tort reformer, but there's been a lot more and more extensive tort reform in other states since this was adopted in 1986.

So we gave some examples in our brief. There certainly are states that just don't allow punitive damages, there are those that require criminal conduct, establishing criminal conduct, and then there are those that don't have clear and convincing evidence, but have a criminal conduct requirement, like Illinois, then there are those who have clear and convincing evidence, but not high probability of injury. So there's a whole range of different state standards and they would have different requirements, potentially, about, you know, whether -- how you impute a statement or an act to a corporation, like we've got our own rules about that, and their own case law around it.

Our position is the plaintiffs can't meet even the most minimum of those standards, which would be maybe a gross negligence standard, with the evidence they've put forward, but their premise that Minnesota law would apply to all cases is just wrong.

MAGISTRATE JUDGE NOEL: Okay. But I'm not sure I got the concession from you that I was trying to get.

MR. HULSE: I'll see if I can give it.

MAGISTRATE JUDGE NOEL: But there are states that do not have a substantive requirement. There are states

where you can just file a complaint and allege you want the following relief: injunctive relief, compensatory damages, punitive damages. In those states, presuming they go through the motions of making the motion to amend to add a claim for punitive damages, those motions from plaintiffs who reside in those states, their motions would be granted.

MR. HULSE: Disagree still, Your Honor, sorry, and that's because every state just based on our research has some elevated requirement for alleging punitive damages. Many states, of course, wouldn't require you to seek leave to amend, but in this MDL because of this pretrial order and the precedent, the post-***Mirapex*** precedent, everybody still has got to make a *prima facie* showing. It may or may not be deliberate disregard, high probability, all those pieces. So it's complicated, which is why I'd like to turn to Ramsey.

JUDGE LEARY: So what are the cases that -- where you believe that conflict-of-law analysis is not at issue and the federal court can reach its merits? Are they only those that have been filed directly in Minnesota?

MR. HULSE: Conflict of laws is an issue for every single case in the federal MDL.

MAGISTRATE JUDGE NOEL: But not for Judge Leary.

MR. HULSE: Right. Judge Leary, it's simpler. There are cases, including two out of the three bellwether

nominees, where plaintiff's in Minnesota, obviously defendant's in Minnesota, surgery was in Minnesota. I think Minnesota law is going to apply there.

However, there are cases where the surgery at issue is not in Minnesota. One of the three bellwether nominees, the surgery is in South Dakota. And so there I don't think you can take for granted that Minnesota law is necessarily going to apply. There's going to be a fact-intensive look at whether when you apply Minnesota choice-of-law rules it's going to choose South Dakota law in that instance.

JUDGE LEARY: So what are you suggesting? Are you suggesting that there's any cases in Ramsey County? I think you are.

MR. HULSE: Yes.

JUDGE LEARY: That there are some cases in Ramsey County where I can reach the merits of the motion to amend --

MR. HULSE: Yes.

JUDGE LEARY: But there are also cases where I may not be able to because of choice of law.

MR. HULSE: Yes, a choice-of-law analysis would have to be conducted.

JUDGE LEARY: Before allowing --

MR. HULSE: Right. And it's possible if the

parties worked on it together, maybe we could find some agreement about ones that we think Minnesota law definitively applies to, but we might have disputes about others.

JUDGE LEARY: Well, wouldn't it make sense to identify those cases where any order that I might issue does in fact apply and allow Plaintiffs to amend the complaint?

MR. HULSE: Well, we don't think they should be allowed to amend the complaint, but putting that aside --

JUDGE LEARY: No, but I'm just talking about reaching the merits of the argument.

MR. HULSE: Right. Yes.

JUDGE LEARY: So I've got 55 cases. I take this under advisement. You're saying that if in fact the law could be applied as Minnesota's law, what are those cases for which my order is going to have application?

MR. HULSE: Right. We don't have those ready today to identify to you, and I would suggest that's something perhaps the parties could confer on and provide to you to see where we have disputes and where we don't have disputes.

JUDGE LEARY: It would seem to me that it's important that you first identify that before this Court begins to consider the merits of the application.

MR. HULSE: My submission is that the plaintiffs

made this motion and that they should have addressed the choice-of-law issues up front. But being that as it may, certainly we have to address them now if the Court's going to consider this. Our submission is, of course, that this is not a close call and that these motions can be denied for both the MDL and for Ramsey County.

JUDGE LEARY: I guess I'm still struggling with the idea -- I mean, theoretically, it may be that because of considerations of conflicts of law we don't reach the merits on any case, but maybe there is a subset of cases where Minnesota law does apply and then we can reach the merits. But until we know that, we don't know where we stand. I mean, I'm not going to issue an order saying -- I'm not going to give, frankly, an advisory opinion as to what I think the law is as applied to the conduct of 3M if I don't have a case to which I can attach that.

MR. HULSE: Right. And, Your Honor, this speaks to this unusual posture of this motion that in ***Mirapex***, for example, ***Levaquin*** -- ***Levaquin*** was about a single bellwether, ***Mirapex*** was about 15. There was a choice-of-law analysis up front. It's a small subset of cases, not 2,000, not 55. You're dealing with a smaller group of cases that presented more manageable conflict-of-laws issues.

MAGISTRATE JUDGE NOEL: So let me ask this question: I'm not sure I'm following what the parties think

we're doing here today.

Is this motion only directed to the bellwether nominees, or is it directed to the entire universe of 2,000 or whatever we're up to in the MDL?

MR. HULSE: It's -- and I'll let Ms. Conlin speak, but it's all, and Plaintiffs argued in page 2 of their brief that Minnesota law applies to all 1800, 2,000 cases in the MDL.

MS. CONLIN: And just to clarify, what we're attempting to do is amend the master complaint. Minnesota is the forum state for that master complaint, and as a result the Minnesota procedural requirements apply to the amendment of that complaint.

If you look at the ***Levaquin*** case, Judge Tunheim said that is a procedural issue and can be governed by Minnesota law.

MAGISTRATE JUDGE NOEL: Okay.

MS. CONLIN: We don't need to get into this conflict-of-laws analysis with respect to individual cases for the purposes of amending the master complaint.

MAGISTRATE JUDGE NOEL: Thank you.

Were you done, Mr. Hulse?

MR. HULSE: I was going to say that's not what ***Levaquin*** said at all. ***Levaquin*** said -- and this is -- and we pointed this out in our brief. But the plaintiffs put in

some bracketed text in their citation to ***Levaquin*** to say that Judge Tunheim's holding was in this MDL or in this litigation. They excised the words "in this case." It was a one-case bellwether determination, and that's what went up to the Court of Appeals and got reversed.

MS. CONLIN: May I just take --

MAGISTRATE JUDGE NOEL: Hold on one second.

MR. HULSE: Yes, Your Honor.

MAGISTRATE JUDGE NOEL: Okay. Thank you. It was more than 15 minutes --

MR. HULSE: And I apologize.

MAGISTRATE JUDGE NOEL: -- but shorter than what Plaintiff did, so you're good to go.

MS. CONLIN: I'll stand by my comments on ***Levaquin***. Just a couple of follow-up points.

On the expert reports, they cite ***Healey*** and ***Berczyk***. In ***Berczyk***, that was a case in which there wasn't any evidence. The lawyer put in an affidavit arguing punitive damages. That's not what's happened here. We've put in the full expert reports for the Court's view. And even in ***Levaquin*** they tried to do that and Judge Tunheim said ***Berczyk*** does not, as Defendants suggest, stand for the proposition that an expert cannot be considered evidence warranting a right to assert punitive damages.

Second -- and I just want to go back to what Judge

Leary was asking about. We're not relying on a single study for the purposes of this amendment. We are relying on the cumulative, total body of evidence that has been amassed in this case. And in ***Prempro*** there is a direct quote. A jury could find that although each study added to the evidence suggesting a risk of injury, the defendant nevertheless continued to engage in a practice of both inaction and mitigation. That's what we're alleging here.

As to whether these are top officials at 3M, you asked about Mark Scott who was on that e-mail. He's not a guy who works in marketing. He's 3M's global marketing manager. Every single one of the people on our documents -- and we've put the titles in -- are directors or vice presidents or somebody. This isn't a clerk that saw a spill in aisle eight. These are key people at 3M with the ability to make that decision.

Finally, to the point that you made, Judge Leary, about that the FDA hasn't done anything. In ***Mirapex***, in Your Honor's order allowing an amendment on punitive damages, the defendants there pointed out that the FDA has concluded based on information available there is not enough evidence to conclude Mirapex causes compulsive gambling. The inaction by the FDA cannot be the measure by which a motion to grant punitive damages or leave to amend to assert punitive damages can be found, and in fact the documents

speak for themselves. The spin they've put on them is an issue for another day.

JUDGE LEARY: Thank you.

MAGISTRATE JUDGE NOEL: Thank you. Let's move --

MR. HULSE: Your Honors, may I briefly speak to Mark Scott's promotion?

MAGISTRATE JUDGE NOEL: We'll go back and forth a million times.

MR. HULSE: All right. He's --

MAGISTRATE JUDGE NOEL: So the next thing I have is the defendants' motion to de-designate documents. Who's up for that?

MS. DAVIES: That would be me, Your Honor.

JUDGE LEARY: Before we go on to the next presentation, I'm going to request that both sides prepare Minnesota state court litigation findings of fact, conclusions of law and proposed order of judgment. I want you to specifically address the issue with regard to conflicts of law and to what extent there are any cases to which the state court decision would apply to a case and identify those cases. And also, I want the law on what is rebuttable evidence and what is not under the law.

And if I may, Judge Noel, how much time do you need to do that?

MR. HULSE: Your Honor, given the choice-of-law

analysis, I'd request two weeks to do it.

MS. CONLIN: Two weeks is fine with us.

JUDGE LEARY: Simultaneous submissions then?

MS. CONLIN: Sure.

JUDGE LEARY: Okay. Whatever it is two weeks from today's date, May 18th, that's the due date.

MR. HULSE: Very good, Your Honor.

JUDGE LEARY: Thank you.

MAGISTRATE JUDGE NOEL: Give me those too, what he said.

(Laughter)

MS. DOHM: Your Honor, if we could -- before you start, if I could just have a couple minutes to open up my briefcase and put my papers down before she would start talking, I would appreciate that.

MAGISTRATE JUDGE NOEL: If you do it quickly.

(Pause)

MAGISTRATE JUDGE NOEL: Okay.

MS. DAVIES: Good morning again. Monica Davies on behalf of defendant 3M. I'm sensitive to the time constraints here this morning. There's obviously a lot going on, so I'm going to try to be as brief as possible.

The issue before the Court here in our view is very simple. Ridgeview has produced documents in this litigation subject to the requirements of the protective

order that it's designated as confidential. 3M doesn't take issue with the vast majority of their designations, but as to the small subset of documents that we're dealing with in this motion, we submit that the confidential designation is inappropriate.

First off, the protective order requires that any party seeking confidentiality has the burden of articulating a good-faith basis for that designation. Ridgeview didn't do that and in the first instance even included e-mails that were sent to the *Star Tribune* for publication in the documents it designated as confidential. We were able to eventually work that out through our meet-and-confer efforts and those documents are not part of our motion. But as to the remainder, they stood by their confidential designation and in our view just did not really articulate a reason why.

Ridgeview in the face of 3M's motion now takes the position that it routinely keeps its documents and confidential health information confidential and that it considers all of the documents at issue in 3M's motion to be confidential business records. But calling the documents confidential isn't enough. Simply having a policy to maintain them as confidential also isn't enough. It doesn't bring them within the definition of confidentiality for purposes of the protective order or for Rule 26(c) of the Rules of Civil Procedure.

We're not talking about patient health information. We're not talking about sensitive corporate or financial data for the hospital or other sorts of competitive or proprietary information that would typically be entitled to protection. We're talking about Ridgeview's use of Dr. Augustine's HotDog warming system, its switch to that product from the Bair Hugger warming system, and public representations that have been made about that switch and about Ridgeview's experience with the products. Those representations have been made in certain instances with Ridgeview's full knowledge and participation; for example, the *Star Tribune* article that was published in 2011.

And the documents also include explanations and indications about the relationship between Dr. Augustine and Ridgeview underlying all of this. The information has already been disclosed and discussed publicly in numerous forums and it has not been kept confidential in the past. Ridgeview has failed to articulate a basis to drop a cloak of confidentiality now.

The fact that both Ridgeview and Dr. Augustine have commented on these issues -- the fact is that both Dr. Augustine and Ridgeview have commented on these issues in the press. Augustine in particular reported to the *Star Tribune* that Ridgeview's use of the HotDog product and its switch to that product from the 3M Bair Hugger system

resulted in a drastically reduced infection rate for the hospital. To this day he claims that that is the case and believes a causal relationship exists and continues to maintain that's a fact, and says that Ridgeview simply doesn't know what it's talking about to the extent that it claims otherwise.

Ridgeview's documents confirm that, yes, they had a positive experience with the HotDog system, but similar to what you saw with the discussion of the McGovern study earlier, there were several factors that went into play with the reduction in infection rates and several initiatives that the hospital took in order to maintain its level of patient care. To say that the HotDog product versus the Bair Hugger product, which is the claim that Dr. Augustine has made repeatedly and the claim that underlies many of the theories that Plaintiffs are advancing in this litigation, is simply not accurate, and that's borne out by the Ridgeview documents that are at issue in this motion.

Ridgeview also claims that it hasn't participated in any kind of study with Dr. Augustine with respect to these issues. Dr. Augustine recently testified, though, that he has submitted the Ridgeview results for publication. We don't know in what journal and it remains to be seen. He was asked about that, but did not want to identify it. This is the same data that Dr. Augustine initially relied upon

when he created a litigation guide for purposes of encouraging Plaintiffs' attorneys to sign on and pursue litigation against 3M, and in that guide he actually refers to and compares this Ridgeview data to the McGovern study that as we've all heard this morning is a critical aspect of this case. And again, similar to what the McGovern study actually says about there being a number of factors that resulted in a drop in infections, the Ridgeview documents show the same thing.

In our view, these are just a few of the examples of the ways in which these documents and their contents have already been made public, which under the terms of the protective order mean that there's no confidentiality to attach. And even aside from the public disclosure, we would submit that the documents themselves simply don't fit the criteria for the protection that's afforded by the order or Rule 26(c). There's no presumption of confidentiality here; in fact, it's just the opposite, and in our view Ridgeview has not offered a sufficient basis why these documents should be protected in this instance.

For that reason, 3M's motion should be granted.

Plaintiffs don't appear to oppose the motion. They certainly haven't filed anything in opposition.

And as for Dr. Augustine, he does oppose 3M's motion. He echoes Ridgeview's interest in keeping its

documents confidential as a general matter, but has taken the position that 3M is somehow improperly trying to take or seek discovery from Dr. Augustine through this motion while Dr. Augustine sits idle, leaving aside the fact that 3M is not seeking anything from Dr. Augustine through this motion and anything we need or are seeking the Court's leave for from Dr. Augustine will be addressed separately.

Your Honors have been living with this case a lot longer than I have, but I think it's safe to say Dr. Augustine has been anything but idle when it comes to the issues in this litigation. He's been a factor throughout. And the connection here with the documents that we are discussing for purposes of our motion here today underscores the reasons why 3M's motion should be granted.

With that, absent any questions, I will take my seat.

MAGISTRATE JUDGE NOEL: Okay. Thank you.

MS. DAVIES: Thank you.

JUDGE LEARY: Thank you.

MS. DOHM: Well, Your Honors, first I'd like to state that obviously Ridgeview --

MAGISTRATE JUDGE NOEL: Hold on one second. There's a button on the front of the podium and there's an arrow that goes down, and if you would lower that so your microphone is -- there you go. Thank you.

MS. DOHM: Thank you.

MAGISTRATE JUDGE NOEL: Keep your voice up.

MS. DOHM: Thank you for that.

MR. LEARY: We don't have that in state court --

(Laughter)

MS. DOHM: Thank you, Your Honor.

And as you both know, Ridgeview Medical Center is not a party to this litigation nor are we privy to any of the proceedings of this litigation. We were served with a subpoena and we met and conferred significantly with 3M to comply with that subpoena and to produce documents that would not be overly burdensome and broad on Ridgeview. We were happy that 3M worked with Ridgeview as it related to allowing us to narrow the scope of the documents that had been originally subpoenaed.

And we thought that that was really the end of it. We went through significant expense and time to gather those documents. We went through significant expense and time to sift through the documents. And we were very thoughtful about those documents that we designated as confidential and those documents that were not designated as confidential.

3M is not Ridgeview. That sounds like an obvious statement, but they're not Ridgeview. They can't tell Ridgeview that documents that are kept in the normal course of their business on their computer systems cannot be kept

as confidential. Their counsel can't make that argument. Their counsel doesn't know how Ridgeview operates.

Ridgeview is a large, complex healthcare organization. There are two hospitals, there are multiple clinics, there are multiple other partnerships, joint ventures, other types of arrangements that Ridgeview has within its organization. It is a very large community hospital organization. It has many, many, many policies and procedures as far as complying with HIPAA and complying with its obligation to keep its documents as confidential.

JUDGE LEARY: There isn't any health information at issue with regard to this motion?

MS. DOHM: There is not. They did allow us to not have to produce protected health information --

JUDGE LEARY: So HIPPA doesn't apply.

MS. DOHM: HIPPA is not an issue here.

What is an issue here is its business dealings, its confidential documents as running its business of Ridgeview. The documents that have been marked as confidential are internal documents within its business organization just like every business in our country has a right to run and have documents kept on its computer system, e-mail within its organization, that is not subject to public disclosure.

Ridgeview produced documents responsive to the

subpoena and designating them as confidential with the understanding that they would understand, basically, that this is a business that runs. Bob Stevens, those individuals that are -- the e-mails that are at issue have to do with the CEO or president of the company and other individuals within the management organization. Any business in our country cannot be opened up for disclosure. If this motion is granted, it's no different than going into any business --

JUDGE LEARY: And for me you don't have to make the larger argument.

MS. DOHM: Okay.

JUDGE LEARY: I'm more interested in the specific argument. The argument is made that information in which Dr. Augustine and Ridgeview collaborated has been placed into the public forum because of that. There's no objection from Ridgeview as to Dr. Augustine doing that. That information should lose its confidentiality. That's what I'd like to hear from you.

MS. DOHM: Okay. Thank you, Your Honor, for that clarification.

So I think we do have some dispute here as to Ridgeview's agreement to put anything into the public forum. I think there's a dispute here as to what Ridgeview's participation or lack of participation was.

There was not a study. There was -- I'm not even sure what she's exactly referring to, but Ridgeview never did participate in a study. So --

JUDGE LEARY: What was the relationship between Dr. Augustine and -- him personally or his company and Ridgeview? They engaged in a project together. I think there's been a reference that had something to do with the HotDog, Dr. Augustine's product. And Dr. Augustine publicly used information gathered from this collaboration for the purpose of touting the HotDog and attempting to undercut the Bair Hugger. I mean, that's the way I understand it's been teed up. If I'm wrong --

MS. DOHM: Yes. I don't believe that there was the collaboration that you may think that there was a collaboration of, as there was never a study. There was discussion of it, but it was never entered into.

JUDGE LEARY: You're looking to somebody. Who's the person --

MS. DOHM: So Ms. Hauser is a representative of Ridgeview Medical Center that is here.

JUDGE LEARY: Well, unless you state it for the record, don't rely on anybody else for the comments that you're making. I need to hear from you.

MS. DOHM: Yes, and my understanding is there was not a collaboration as far as any study ever being entered

into.

MAGISTRATE JUDGE NOEL: Well, let me ask this question, because it appears that your answer seems to be turning on interpreting the phrase "collaboration."

Did you disclose to Dr. Augustine any of the data, any -- as I understand it, there's a total of 50 documents that are at issue. Is that a correct reading of your papers?

MS. DOHM: Yes, I believe that there are a total of about 50 documents.

MAGISTRATE JUDGE NOEL: Did you disclose any of those documents to Dr. Augustine that you have designated as confidential and are therefore limiting what 3M can do with them?

MS. DOHM: To go through each one of these specifically, I believe that certainly certain documents, such as the field advisory agreement, which is marked RMC 50, between Augustine and Ridgeview would have been disclosed to him. Other documents that have been marked as confidential, such as RMC 39, I cannot answer that specifically, but I do not believe that that was disclosed to him.

MAGISTRATE JUDGE NOEL: I have the same concern that Judge Leary does, which is if you -- whether you're collaborating or whatever, if you are disclosing documents

to Dr. Augustine that are not available to the public and that are being designated as confidential because you don't want them to be made public, that's a problem for me I've got to work through, is there a rational basis for disclosing things to Dr. Augustine that you're not being allowed -- that you are not allowing to be disclosed to others.

MS. DOHM: Yes. So addressing that issue, any business in our country may have relationships with third parties that they don't want disclosed to the public. In this case the issue is Scott Augustine, but I would take it to a broader context of any business that operates in this country with vendors or other relationships.

MAGISTRATE JUDGE NOEL: I'm not interested in any business in the country.

MS. DOHM: Yes.

MAGISTRATE JUDGE NOEL: I'm interested in Ridgeview Medical Center's designation of these documents as confidential at the same time that you are disclosing them to Dr. Augustine and, so far as I can tell, not limiting what he can do with them, and maybe that's a mistaken impression I have.

When you disclosed some of these 50 documents to Dr. Augustine, did you limit what he can do with them in the same way that you're seeking to limit what 3M can do with

them?

MS. DOHM: My understanding was that these documents were confidential with that relationship and that he was not to use any of Ridgeview's confidential medical information. Ridgeview has policies --

JUDGE LEARY: Well, when you say "my understanding," I mean, that's -- I don't know what that means. What's --

MAGISTRATE JUDGE NOEL: What's your understanding based on?

MS. DOHM: My understanding would be based on how Ridgeview operates its business. If you look at documents that we submitted in support of the opposition to this motion, there are documents such as vendor policies, other documents, that talk about Ridgeview maintaining the confidentiality of its business documents with third parties. That's Ridgeview's intent.

As far as Mr. Augustine's intent, I can't speak as to that. I can only speak as to my client's intent, but my client's intent is that when it does do business with vendors such as Mr. Augustine, that those documents would be kept confidential.

JUDGE LEARY: Well, all you're telling us is your understanding as to the way Ridgeview generally does business. You're not telling us anything with regard to how

Ridgeview was doing business with Dr. Augustine with regard to the information you seek to keep protected. You're not telling us that.

MS. DOHM: I don't believe that there's an e-mail that exists specifically with that direction to him, if that's what you're asking me.

JUDGE LEARY: I'm just asking for what is Ridgeview's position with regard to claiming that this information should be protected. That's all I'm saying. I'm not going to give you the universe of possibilities or hypotheticals that I can present. I want to know the information upon which Ridgeview is relying, and I'm not hearing that you know that.

MS. DOHM: Well, I think one issue that I would like to bring up is, I don't believe -- at least I'm not aware of all of these 50 documents that he did use. I haven't been presented with that evidence, that he has all of these documents in his possession from a former relationship with Ridgeview going back at the time of this issue. So I disagree that Mr. Augustine has all of these documents in his possession from a previous time period.

MAGISTRATE JUDGE NOEL: But as I understood your answer to my earlier question, at least some of the documents, some of the 50, have been disclosed to Dr. Augustine. Is that a correct statement?

MS. DOHM: I would agree with that. To the extent that there are e-mails between the two, to the extent that there are signatures of contracts, I would agree that that would be logical, that yes, they would have been disclosed to him.

JUDGE LEARY: And do they all relate to the same subject matter? And if so, what is the subject matter that they relate to?

MS. DOHM: There was discussion of a relationship between those parties.

JUDGE LEARY: Ridgeview and Dr. Augustine.

MS. DOHM: Yes, that did not -- regarding a study that never came to fruition.

JUDGE LEARY: And what study was that?

MS. DOHM: Honestly, I can't speak and answer that question without Ms. Hauser answering that question.

(Discussion off the record between the judges)

IN OPEN COURT

THE COURT: Okay. Thank you. Anything else?

MS. DOHM: We believe that under Pretrial Order Number 7 that the documents that Ridgeview has designated as confidential do meet the definition of confidential under Provision 2 of the order.

To the extent that the Court would decide to publicly disclose confidential business documents of

Ridgeview, that would harm Ridgeview Medical Center. Ridgeview Medical Center holds all of its business documents, its dealings with its vendors, in confidence. That is how it operates its business.

MAGISTRATE JUDGE NOEL: Okay. Thank you.

Anything else?

MS. DAVIES: Can I be heard very briefly?

MAGISTRATE JUDGE NOEL: Thirty seconds.

MS. DAVIES: I'd like to just address a couple of the questions that were raised by Your Honors.

First of all, with respect to your question, Judge Leary, our position is yes, all of the documents that are at issue in our motion do relate to the same subject matter, and that is Ridgeview's use of the HotDog warming product, its experience with that versus Bair Hugger, the reasons why it was engaged in this exchange with Dr. Augustine in the first place.

With respect to Counsel's reference to RMC 39, which is a document attached as Exhibit E to the Hulse declaration, that is the infection data that has been -- that's comprised much of the discussion publicly. Whether that specific physical document was turned over to Dr. Augustine I don't know, but the information contained in that document certainly was, because that is the subject matter of the *Star Tribune* article about which there were

many exchanges between Ridgeview and Dr. Augustine, and in that article there is a specific reference to Ridgeview's experience going from 1.55 percent to 0.29 percent infection rate, which is an 81 percent reduction.

The *Star Tribune* reached out to Ridgeview for comment. Ridgeview indicated that it had a positive experience with the HotDog product. However, there is no data to support a direct correlation to that product and our reduced infection rates.

Dr. Augustine contacted Ridgeview, said he wasn't happy with that comment, thought it undermined his credibility, thought it cost Ridgeview a chance for good PR. And internally, again, at issue in the documents here and those I believe you can find at Exhibit D to the Hulse declaration is a series of exchange and discussion and I would say collaboration as to how that experience should be publicly represented.

MAGISTRATE JUDGE NOEL: Okay.

MS. DAVIES: With that I am done unless you have any questions.

JUDGE LEARY: I'm good. Thank you.

MS. DAVIES: Thank you.

MR. BENHAM: Did you want me to speak, Your Honor?

MAGISTRATE JUDGE NOEL: Not on this issue. I will take your -- you filed a memo, correct?

MR. BENHAM: I did.

MAGISTRATE JUDGE NOEL: So we need your memo, but I don't want to prolong -- I think I understand everybody's position and we'll get to you when the next motion comes up, which is the motion to take longer or more depositions of Dr. Augustine, et al. And who's this one --

MR. BLACKWELL: That will be Mr. Gordon, Your Honor.

MAGISTRATE JUDGE NOEL: You're just the general manager.

(Laughter)

MR. BLACKWELL: Yes. That was awkward.

MR. GORDON: Good morning for the moment, Your Honors. And because it is almost noon, I will try to be as brief as possible.

First let me address the Scott Augustine additional deposition time issue.

The federal rules have a presumptive seven-hour time limit and that can be extended basically under two circumstances. One is if there's been obstruction or unnecessary delay. That is not a basis of our argument. Actually, this is one of the few depositions I've been in where I can't say that there was any filibustering.

MAGISTRATE JUDGE NOEL: Do me a favor real quick. You're a taller man and --

MR. GORDON: Oh. Yeah, you're right.

MAGISTRATE JUDGE NOEL: Just raise that up a tad.

(Lectern raised)

MR. GORDON: Oh, that's cool. Thank you.

MAGISTRATE JUDGE NOEL: Thank you.

MR. GORDON: The basis of our motion for some additional time with Dr. Augustine is based on the need to fairly examine the deponent. I don't think it would -- I don't think there's any hyperbole I could come up with that would be inaccurate in describing the centrality of Dr. Scott Augustine to virtually every issue extant in these thousands of cases pending before each of your courts.

Dr. Augustine, because his involvement with the Bair Hugger goes back more than 30 years to the development of it, to the early testing, that 510(k) that we heard about earlier this morning, well, that was Dr. Augustine. We didn't even get to that in the seven hours. There's so many other issues that are more current and more central, but it's one of the issues that we would have liked to at least explored a little bit of -- taken a little bit of time exploring with him.

Fast forward to the last 15 years or so when Dr. Augustine shifted his focus to achieving a competitive advantage for his product, the HotDog, and the intense involvement of Dr. Scott Augustine personally as the

architect not just of the science -- and his hands are on every single one of the studies that Plaintiffs rely on heavily -- but as we learned shortly before his deposition was taken, of his direct and heavy involvement in orchestrating and being the architect of the litigation front, weaponizing lawyers and lawsuits as a competitive marketing tool.

We covered a lot of areas with Dr. Augustine in seven hours. We covered 314 or 317 pages of transcript. We got through 70 exhibits. It's an average of six minutes per exhibit. We didn't waste any time. We didn't venture into frivolous areas or irrelevant stuff, but he's just -- he's involved in so much and there's so many documents, so many things that involve him, that seven hours just wasn't enough as expeditiously as we tried to do it, in addition to some of the early stuff that we just, you know, put to the end, the 510(k). A lot of the stuff about his orchestration of those studies we didn't drill down on, a lot of the stuff about his heavy involvement in deciding, okay, well, this study's been --

MAGISTRATE JUDGE NOEL: How much time are you asking for?

MR. GORDON: We suggested four hours. Three probably would be sufficient. And --

JUDGE LEARY: You better ask for enough so you

don't come back again.

MR. GORDON: I'd rather have four. I would rather have four.

And before tummies start growling, I'll stop, because I don't want to belabor the point. And I don't know if Your Honors would prefer a response to this, or if I should just go right into the two additional depositions.

JUDGE LEARY: Go ahead.

MR. GORDON: I will do that.

The two additional depositions are Mr. Benham, Randall Benham, Mr. Augustine's attorney -- Dr. Augustine's attorney, and Brent Augustine, who's Dr. Augustine's son.

We did not make an effort to take their depositions earlier in the discovery phase for a couple reasons.

Number one, as a general rule, I try to avoid taking depositions of lawyers, because a lot of times you run into attorney-client privilege issues and it becomes a waste of time, so if you can get the information some other way, it seems to be a lot more effective.

And number two, we just -- earlier in the litigation we didn't have documents that clearly linked Mr. Benham and Brent Augustine to critical issues in the case -- and particularly in the case of Mr. Benham -- in a way that clearly would not be subject to attorney-client

privilege objections.

Once we got those documents -- literally, I think it was five business days before the close of discovery -- we went through them quickly and we thought, well, we probably ought to take their deposition. So we did send out a notice for the last day of the discovery period knowing that -- we already knew that that date wasn't going to work for the parties because we had tried to schedule Dr. Scott Augustine's deposition that day. That didn't work and by agreement we continued that a few days and we hoped to do the same.

And the other reason I want to just briefly address, because there's I guess a criticism that we didn't try to take their depositions earlier.

I'm actually -- I believe in Federal Rule of Civil Procedure 1. That's one of the -- the prime directive. I feel like I'm Star Trek here anyway with this module. But if there's no need to take somebody's deposition, if you can get -- if we can get the information from someone else or through some other means, it's a waste of time, money, and imposition, particularly on a nonparty, although to characterize Dr. Augustine and his employees as nonparties is stretching the term a little bit.

But the point is that we didn't just immediately start trying to depose everybody connected to Dr. Augustine.

We deposed Dr. Augustine with a good-faith expectation that he would be able to answer essentially all of the questions that we would have otherwise directed to Mr. Benham and to his son Brent Augustine. And in several instances he surprisingly would say, "Well, I had nothing to do with that," you know, "That was Mr. Benham" or, "You'd have to ask Mr. Benham that" or, "You'd have to ask Brent." He didn't do a lot of that with Brent.

And in candor to the Court, if Your Honors decide that, you know, Brent Augustine is not a crucial witness and, you know, we missed our opportunity, I would accept that.

Mr. Benham is a different story, integrally involved in the orchestration of litigation and writing the handbook to lawyers, working with plaintiffs' lawyers and scoping out questions for 3M employees before their depositions, things like that. Again, we thought Dr. Augustine would know -- the website, all those sorts of things. We thought Dr. Augustine would be able to answer a lot of those questions. He did many of them, but many of them he laid it at the doorstep of Mr. Benham.

And I'll anticipate a question. I guess we would like three hours with Mr. Benham since he has been defending -- he defended Dr. Augustine's deposition. I presume if we are granted leave to take additional time with

Dr. Augustine, he'll be there for that. Could probably knock it down in one day, four hours with Dr. Augustine in the morning, three hours with Mr. Benham in the afternoon or vice versa, whatever works.

Rather than go too far into the lunch hour, I'm going to stop unless Your Honors have any questions.

JUDGE LEARY: So are you withdrawing your request to depose Dr. Augustine's son?

MR. GORDON: We would like an hour with Dr. -- I mean with Brent Augustine. And I'm just trying to be practical. I can say that the questions we have for him would be fairly limited.

MAGISTRATE JUDGE NOEL: Okay. Thank you.

MR. GORDON: Thank you.

MAGISTRATE JUDGE NOEL: Mr. Benham?

MR. BENHAM: Addressing the question of allowing additional time for Dr. Augustine first, I'd just like to point out that it was 18 months, maybe two years ago that you issued the order that one hour of Dr. -- excuse me -- one day, seven hours, of Dr. Augustine was all that was allowed when they were asking for additional time at that amount.

Since then Dr. Augustine has been available for deposition. His deposition was scheduled at least six times. We prepared for it. We made him available at least

six times, and each time counsel for 3M cancelled it, sometimes on very short notice. That, I presume, is a strategy. The strategy of waiting until the last day or in fact a week after the last day to take Dr. Augustine's deposition I presume was also a strategy, as was the largely wasted seven hours that they spent.

As I pointed out, on 89 separate occasions counsel for 3M read and read and read and read from technical papers and from research papers and had simply the question: "Did I read that correctly?" at the end of it. While counsel certainly has the right to use their time any way they want, I suggest that in this case it was largely wasted and I hope you'll take that into consideration.

As regards the extension of discovery to take my deposition and the deposition of Mr. Augustine, I wonder whether I really have standing to even have an opinion on that. That's largely something between the Court and the parties.

I would just point out that, again, Mr. Augustine and I have been available to be deposed for the last two years and were available to be deposed that last week in which the parties determined that they would extend discovery by a week by my consent.

Other than that, I don't have anything else to add.

MAGISTRATE JUDGE NOEL: All right. Thank you.

Do the plaintiffs have a position on any of this?

MR. SACCHET: We do.

Good afternoon, Your Honors. Michael Sacchet on behalf of Plaintiffs.

Under all the authority that we've cited in our memorandum in opposition to 3M's motion, 3M has failed to show good cause for the relief that it seeks in seeking to depose Dr. Augustine beyond the seven-hour maximum and after the discovery deadline. And the same holds true with respect to the additional depositions of Mr. Benham and Mr. Brent Augustine.

For example, in ***Jensen vs. AstraZenica***, Your Honor, the defendant Bayer moved to depose the plaintiff beyond the seven-hour maximum and you denied that request, and Judge Tunheim affirmed it. And the rationale behind that decision was: All of the questions that could have been asked at the initial deposition or during the subsequent deposition could have been asked at the initial deposition. And when that's the case, a party does not have good cause to simply just redepose that same witness.

And I've listened to Mr. Gordon's argument and the argument essentially boils down to: We had more documents and we had more questions. Those documents, those questions, have been known since the very beginning of this

case, if not well before it. Mr. Gordon cited a 510(k) document that dates back to the 1980s or 1990s. That was one of the first documents that 3M produced to Plaintiffs in this litigation. If it was so paramount, in Plaintiffs' view, it should have been part of the set of questioning that was asked of Dr. Augustine during his first deposition.

As to the other witnesses, there's also law to support the fact that when a party attempts a wait-and-see strategy of essentially asking some questions, seeing what comes out and then asking to redepose a witness, that too does not constitute good cause.

And here, in 3M's brief they expressly argue that it was reasonable for it to expect that Dr. Augustine would have the requisite knowledge to answer all of the questions that were put to him at the deposition, and just because he was unable to answer some of those questions, to now ask for Mr. Benham's deposition and Mr. Brent Augustine's deposition months after the discovery deadline doesn't show a good cause. And a number of district court cases that we've cited along with the Eighth Circuit have held that the wait-and-see approach is simply a tactical failure, and as such it does not constitute good cause.

The last thing I would like to note -- and I am doing my best to be brief -- is that 3M has cited just two cases in its memorandum, only two cases, neither one of

which is from this district. One is from the Court of Federal Claims, the other is from the United States District Court for the District Court of Columbia. In both such cases, they're plainly distinguishable on their face. I could talk about 30 minutes about how they are distinguishable, but there's one key point, one key point:

In neither case, in neither one of them, did the moving party ask to depose a witness after the close of discovery. 3M's motion is not just noted under Rule 30(d), it is also brought under Rule 16(b)(4), and neither one of the cases that they've cited has anything to do with it.

So, in light of those two things, we ask that 3M's motion be denied. To the extent that it is granted, we have noted in our papers a request to depose two other witnesses, Al Van Duren and Mr. Mark Albrecht. We realize we have not filed a formal motion to that effect, but even in the case that 3M has cited in support of its motion recognized that proposition that an oral request to depose a witness at a hearing such as this may be granted by a court in its discretion.

Thank you.

JUDGE LEARY: Let me ask you: Why was Dr. Augustine's deposition concluded? Was it because they had run up against seven hours, or did Mr. Gordon represent that he --

MR. SACCHET: No. That is a good question, Your Honor, and Mr. Gordon did in fact express the sentiment that he was not done questioning. I will represent to you that I do believe the deposition even did surpass seven hours. Both Mr. Benham and Plaintiffs' counsel let Mr. Gordon go a few more minutes than the seven-hour maximum, and now they've brought this motion.

One last point is that in light of what Mr. Benham said earlier about the scheduling of Mr. Augustine's deposition, it was rescheduled numerous times and there's one part I want to make note of.

The deposition was amended -- an amended notice was sent by 3M to depose Dr. Augustine on January 9th. 3M cancelled the deposition on December 30th. It did not renotice the deposition until sometime in February and set that date for March 10th. I mean, a two and a half month delay to renotice the deposition that it ended up taking on an extension of the discovery deadline, and then now to come back and ask for four more hours or perhaps three I think strains credulity.

MAGISTRATE JUDGE NOEL: Thank you.

JUDGE LEARY: Thank you.

MAGISTRATE JUDGE NOEL: Mr. Gordon, anything else?

MR. GORDON: Very briefly, Your Honor.

The order that Your Honor Judge Noel issued a year

and a half ago was in connection with one or two individual cases that had been filed at that point. Virtually no or very limited written discovery had been -- had occurred. Virtually no written discovery --

MAGISTRATE JUDGE NOEL: What about the six cancellations, though?

MR. GORDON: There were a lot of scheduling issues and they were also related -- this is an important point -- they were related to production of documents. We were getting -- the document production process from Dr. Augustine and his related companies was not a smooth process, as I think Your Honor some insight into. So we have the expectation that the documents would be available, we'd try to schedule depositions because, you know, this is like herding cats trying to get something scheduled with all the various lawyers involved. The document production would be incomplete. We'd go have meet-and-confers. You get the picture.

As to the seven-hour limit, one thing I've learned is that the plaintiffs are extraordinarily good timekeepers, because this wasn't the first deposition where they were at the -- you know, towards the end saying, "Mr. Court Reporter, what time are we at?" "Six hours and 47 minutes." "What time are we at?" "Six hours and 52 minutes." Literally, when we got to 6:59 -- maybe not this deposition,

but they were saying, "Okay. You got one minute left." They're very, very good at keeping time. And so it was terminated. Mr. Benham did allow Ms. Conlin to ask a few questions because she hadn't had any chance.

I don't know if -- I don't think there's a motion before Your Honors with respect to the additional deposition, so I'm not -- all I will say is Mr. Van Duren has been deposed five times already.

Thank you, Your Honor.

MAGISTRATE JUDGE NOEL: Okay. Thank you all very much. There's one more statement that Judge Ericksen has asked me to make for the record.

On May 10th, the defendants filed a motion to dismiss for failure to comply with Pretrial Order Number 14, and she asked me to confirm on the record that that motion will be heard at the June status conference.

Everybody got that?

MR. BLACKWELL: Yes, Your Honor.

MAGISTRATE JUDGE NOEL: Now, give me two minutes to chat with Judge Leary.

(Discussion off the record between Judge Leary and Magistrate Judge Noel)

IN OPEN COURT

THE COURT: So we're going to take everything under advisement except for the last motion. The motion on

the depositions, we're going to rule right now.

We will order that Dr. Scott Augustine be deposed for an additional four hours, Mr. Benham will be deposed for three hours, and Brent Augustine for one hour. Everything else is under advisement and we will be entering orders in due course.

Thank you all very much for a fascinating and interesting argument and we are in recess.

JUDGE LEARY: Thank you.

(Proceedings concluded at 12:13 p.m.)

* * * *

C E R T I F I C A T E

I, **TIMOTHY J. WILLETTE**, Official Court Reporter for the United States District Court, do hereby certify that the foregoing pages are a true and accurate transcription of my shorthand notes, taken in the aforementioned matter, to the best of my skill and ability.

/s/ Timothy J. Willette

TIMOTHY J. WILLETTE, RDR, CRR, CRC
Official Court Reporter - U.S. District Court
1005 United States Courthouse
300 South Fourth Street
Minneapolis, Minnesota 55415-2247
612.664.5108